2006

Watch Bills

ASSEMBLY BILL No. 1908

Introduced by Assembly Member Karnette

January 26, 2006

An act to add Section 14105.16 to the Welfare and Institutions Code, relating to Medi-Cal.

LEGISLATIVE COUNSEL'S DIGEST

AB 1908, as introduced, Karnette. Medi-Cal: pharmacy reimbursement.

Existing law provides for the Medi–Cal program, which is administered by the State Department of Health Services, pursuant to which medical benefits, including prescription drugs, are provided to public assistance recipients and certain other low–income persons.

This bill would require the department to reimburse for medications provided to Medi-Cal recipients for intravenous or infusion drug therapy in a manner that is consistent with the services provided, in order to ensure that patients receiving these services continue to receive appropriate care and continuity of their drug regimen.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 14105.16 is added to the Welfare and Institutions Code, to read:

14105.16. The department shall reimburse for medications provided to Medi-Cal recipients for intravenous or infusion drug therapy in a manner that is consistent with the services provided,

in order to ensure that patients receiving these services continue to receive appropriate care and continuity of their drug regimen.

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AMENDED IN ASSEMBLY MARCH 23, 2006

AMENDED IN ASSEMBLY MARCH 20, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 2057

Introduced by Assembly Member Cogdill

February 15, 2006

An act to amend Sections 11100 and 11106 of~~, and to add Section 11383.5 to,~~ the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 2057, as amended, Cogdill. Controlled substances.

~~(1)~~ Existing law generally provides that any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes to any person or entity in this or any other state any of a list of substances shall submit a report to the Department of Justice of all of those transactions, and shall submit an application to, and obtain a permit for the conduct of that business from, the Department of Justice, as specified. Any person who does not submit a report as required, who submits a false report, or who sells, transfers, or furnishes a substance without a permit is guilty of a crime.

Existing law provides, however, that the above reporting requirements are not applicable to, among others, any specified manufacturer or wholesaler licensed by the California State Board of Pharmacy; or any analytical research facility that is registered with the federal Drug Enforcement Administration of the United States Department of Justice; and that the above business permit

requirements are not applicable to, among others, any specified manufacturer or wholesaler licensed by the California State Board of Pharmacy and also registered with the federal Drug Enforcement Agency; any state licensed health care facility, physician, dentist, podiatrist, veterinarian, or veterinary food animal drug retailer licensed by the California State Board of Pharmacy that administers or furnishes a substance to a patient; or any analytical research facility that is registered with the federal Drug Enforcement Administration of the United States Department of Justice.

This bill would delete the exemption from the reporting requirements for specified manufacturers or wholesalers licensed by the California State Board of Pharmacy; and would revise the exemption from the reporting requirements relating to analytical research facilities to provide that the exemption shall apply to any analytical research facility that purchases no more than 200 milliliters of a liquid controlled chemical substance or one kilogram of a solid controlled chemical substance, except in the case of the purchase of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, in which case the facility may purchase no more than 9 solid grams. Because this bill would make existing crimes applicable to a new category of persons or entities, this bill would impose a state-mandated local program upon local governments.

This bill would furthermore delete the exemptions from the business permit requirements for specified manufacturers or wholesalers licensed by the California State Board of Pharmacy; and for any state licensed health care facility, physician, dentist, podiatrist, veterinarian, or veterinary food animal drug retailer licensed by the California State Board of Pharmacy that administers or furnishes a substance to a patient; and would revise the exemption from the business permit requirements relating to analytical research facilities to provide that the exemption from the business permit requirements shall apply to any analytical research facility that purchases no more than 200 milliliters of a liquid controlled chemical substance or one kilogram of a solid controlled chemical substance, except in the case of the purchase of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, in which case the facility may purchase no more than 9 solid grams. Because this bill would make existing crimes applicable to a new category of persons or entities, this bill would impose a state-mandated local program upon local governments.

~~(2) Existing law further provides, with specified exceptions, that it is a felony for any person, with intent to manufacture methamphetamine, to possess ephedrine or pseudoephedrine, a substance containing ephedrine or pseudoephedrine, or other specified chemicals.~~

~~This bill would, in addition, provide that the possession of more than 1/2 pound of ephedrine or pseudoephedrine or their salts or isomers or other specified chemicals is a felony. The bill would include persons as otherwise authorized by law within an exception to these provisions and would provide that possession of specified chemicals sufficient for the manufacture of a specified derivative substance shall be deemed to be possession of that derivative substance.~~ By creating new crimes or revising existing crimes, this bill would impose a state-mandated local program.

~~(3)~~ The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 11100 of the Health and Safety Code is amended to read:

11100. (a) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes any of the following substances to any person or entity in this state or any other state shall submit a report to the Department of Justice of all of those transactions:

(1) Phenyl-2-propanone.
(2) Methylamine.
(3) Ethylamine.
(4) D-lysergic acid.
(5) Ergotamine tartrate.
(6) Diethyl malonate.
(7) Malonic acid.
(8) Ethyl malonate.

(9) Barbituric acid.
(10) Piperidine.
(11) N-acetylanthranilic acid.
(12) Pyrrolidine.
(13) Phenylacetic acid.
(14) Anthranilic acid.
(15) Morpholine.
(16) Ephedrine.
(17) Pseudoephedrine.
(18) Norpseudoephedrine.
(19) Phenylpropanolamine.
(20) Propionic anhydride.
(21) Isosafrole.
(22) Safrole.
(23) Piperonal.
(24) Thionylchloride.
(25) Benzyl cyanide.
(26) Ergonovine maleate.
(27) N-methylephedrine.
(28) N-ethylephedrine.
(29) N-methylpseudoephedrine.
(30) N-ethylpseudoephedrine.
(31) Chloroephedrine.
(32) Chloropseudoephedrine.
(33) Hydriodic acid.
(34) Gamma-butyrolactone, including butyrolactone; butyrolactone gamma; 4-butyrolactone; 2(3H)-furanone dihydro; dihydro-2(3H)-furanone; tetrahydro-2-furanone; 1,2-butanolide; 1,4-butanolide; 4-butanolide; gamma-hydroxybutyric acid lactone; 3-hydroxybutyric acid lactone and 4-hydroxybutanoic acid lactone with Chemical Abstract Service number (96-48-0).
(35) 1,4-butanediol, including butanediol; butane-1,4-diol; 1,4-butylene glycol; butylene glycol; 1,4-dihydroxybutane; 1,4-tetramethylene glycol; tetramethylene glycol; tetramethylene 1,4-diol with Chemical Abstract Service number (110-63-4).
(36) Red phosphorus, including white phosphorus, hypophosphorous acid and its salts, ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium

hypophosphite, sodium hypophosphite, and phosphorous acid and its salts.

(37) Iodine or tincture of iodine.

(38) Any of the substances listed by the Department of Justice in regulations promulgated pursuant to subdivision (b).

(b) The Department of Justice may adopt rules and regulations in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code that add substances to subdivision (a) if the substance is a precursor to a controlled substance and delete substances from subdivision (a). However, no regulation adding or deleting a substance shall have any effect beyond March 1 of the year following the calendar year during which the regulation was adopted.

(c) (1) (A) Any manufacturer, wholesaler, retailer, or other person or entity in this state, prior to selling, transferring, or otherwise furnishing any substance specified in subdivision (a) to any person or business entity in this state or any other state, shall require (A) a letter of authorization from that person or business entity that includes the currently valid business license number or federal Drug Enforcement Administration (DEA) registration number, the address of the business, and a full description of how the substance is to be used, and (B) proper identification from the purchaser. The manufacturer, wholesaler, retailer, or other person or entity in this state shall retain this information in a readily available manner for three years. The requirement for a full description of how the substance is to be used does not require the person or business entity to reveal their chemical processes that are typically considered trade secrets and proprietary information.

(B) For the purposes of this paragraph, "proper identification" for in-state or out-of-state purchasers includes two or more of the following: federal tax identification number; seller's permit identification number; city or county business license number; license issued by the California Department of Health Services; registration number issued by the Federal Drug Enforcement Administration; precursor business permit number issued by the Bureau of Narcotic Enforcement of the California Department of Justice; driver's license; or other identification issued by a state.

(2) (A) Any manufacturer, wholesaler, retailer, or other person or entity in this state that exports a substance specified in subdivision (a) to any person or business entity located in a foreign country shall, on or before the date of exportation, submit to the Department of Justice a notification of that transaction, which notification shall include the name and quantity of the substance to be exported and the name, address, and, if assigned by the foreign country or subdivision thereof, business identification number of the person or business entity located in a foreign country importing the substance.

(B) The department may authorize the submission of the notification on a monthly basis with respect to repeated, regular transactions between an exporter and an importer involving a substance specified in subdivision (a), if the department determines that a pattern of regular supply of the substance exists between the exporter and importer and that the importer has established a record of utilization of the substance for lawful purposes.

(d) (1) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes a substance specified in subdivision (a) to a person or business entity in this state or any other state shall, not less than 21 days prior to delivery of the substance, submit a report of the transaction, which includes the identification information specified in subdivision (c), to the Department of Justice. The Department of Justice may authorize the submission of the reports on a monthly basis with respect to repeated, regular transactions between the furnisher and the recipient involving the substance or substances if the Department of Justice determines that a pattern of regular supply of the substance or substances exists between the manufacturer, wholesaler, retailer, or other person or entity that sells, transfers, or otherwise furnishes the substance or substances and the recipient of the substance or substances, and the recipient has established a record of utilization of the substance or substances for lawful purposes.

(2) The person selling, transferring, or otherwise furnishing any substance specified in subdivision (a) shall affix his or her signature or otherwise identify himself or herself as a witness to the identification of the purchaser or purchasing individual, and

shall, if a common carrier is used, maintain a manifest of the delivery to the purchaser for three years.

(e) This section shall not apply to any of the following:

(1) Any pharmacist or other authorized person who sells or furnishes a substance upon the prescription of a physician, dentist, podiatrist, or veterinarian.

(2) Any physician, dentist, podiatrist, or veterinarian who administers or furnishes a substance to his or her patients.

(3) Any analytical research facility that purchases no more than 200 milliliters of a liquid controlled chemical substance or one kilogram of a solid controlled chemical substance, except in the case of the purchase of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, in which case the facility may purchase no more than nine solid grams.

(4) A state-licensed health care facility that administers or furnishes a substance to its patients.

(5) (A) Any sale, transfer, furnishing, or receipt of any product that contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations adopted thereunder. However, this section shall apply to preparations in solid or liquid dosage form, except pediatric liquid forms, as defined, containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine where the individual transaction involves more than three packages or nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

(B) Any ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine product subsequently removed from exemption pursuant to Section 814 of Title 21 of the United States Code shall similarly no longer be exempt from any state reporting or permitting requirement, unless otherwise reinstated pursuant to subdivision (d) or (e) of Section 814 of Title 21 of the United States Code as an exempt product.

(6) The sale, transfer, furnishing, or receipt of any betadine or povidone solution with an iodine content not exceeding 1 percent in containers of eight ounces or less, or any tincture of iodine not

exceeding 2 percent in containers of one ounce or less, that is sold over the counter.

(7) Any transfer of a substance specified in subdivision (a) for purposes of lawful disposal as waste.

(f) (1) Any person specified in subdivision (a) or (d) who does not submit a report as required by that subdivision or who knowingly submits a report with false or fictitious information shall be punished by imprisonment in a county jail not exceeding six months, by a fine not exceeding five thousand dollars ($5,000), or by both the fine and imprisonment.

(2) Any person specified in subdivision (a) or (d) who has previously been convicted of a violation of paragraph (1) shall, upon a subsequent conviction thereof, be punished by imprisonment in the state prison, or by imprisonment in a county jail not exceeding one year, by a fine not exceeding one hundred thousand dollars ($100,000), or by both the fine and imprisonment.

(g) (1) Except as otherwise provided in subparagraph (A) of paragraph (6) of subdivision (e), it is unlawful for any manufacturer, wholesaler, retailer, or other person to sell, transfer, or otherwise furnish a substance specified in subdivision (a) to a person under 18 years of age.

(2) Except as otherwise provided in subparagraph (A) of paragraph (6) of subdivision (e), it is unlawful for any person under 18 years of age to possess a substance specified in subdivision (a).

(3) Notwithstanding any other law, it is unlawful for any retail distributor to (i) sell in a single transaction more than three packages of a product that he or she knows to contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or (ii) knowingly sell more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, other than pediatric liquids as defined. Except as otherwise provided in this section, the three package per transaction limitation or nine gram per transaction limitation imposed by this paragraph shall apply to any product that is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), or regulations adopted thereunder, unless exempted from the requirements of the federal Controlled

Substances Act by the federal Drug Enforcement Administration pursuant to Section 814 of Title 21 of the United States Code.

(4) (A) A first violation of this subdivision is a misdemeanor.

(B) Any person who has previously been convicted of a violation of this subdivision shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars ($10,000), or by both the fine and imprisonment.

(h) For the purposes of this article, the following terms have the following meanings:

(1) "Drug store" is any entity described in Code 5912 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(2) "General merchandise store" is any entity described in Codes 5311 to 5399, inclusive, and Code 5499 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(3) "Grocery store" is any entity described in Code 5411 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(4) "Pediatric liquid" means a nonencapsulated liquid whose unit measure according to product labeling is stated in milligrams, ounces, or other similar measure. In no instance shall the dosage units exceed 15 milligrams of phenylpropanolamine or pseudoephedrine per five milliliters of liquid product, except for liquid products primarily intended for administration to children under two years of age for which the recommended dosage unit does not exceed two milliliters and the total package content does not exceed one fluid ounce.

(5) "Retail distributor" means a grocery store, general merchandise store, drugstore, or other related entity, the activities of which, as a distributor of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products, are limited exclusively to the sale of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products for personal use both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. "Retail distributor" includes an entity that makes a direct sale, but does not include the parent company of that entity

if the company is not involved in direct sales regulated by this article.

(6) "Sale for personal use" means the sale in a single transaction to an individual customer for a legitimate medical use of a product containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine in dosages at or below that specified in paragraph (3) of subdivision (g). "Sale for personal use" also includes the sale of those products to employers to be dispensed to employees from first-aid kits or medicine chests.

(i) It is the intent of the Legislature that this section shall preempt all local ordinances or regulations governing the sale by a retail distributor of over-the-counter products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

SEC. 2. Section 11106 of the Health and Safety Code is amended to read:

11106. (a) (1) (A) Any manufacturer, wholesaler, retailer, or any other person or entity in this state that sells, transfers, or otherwise furnishes any substance specified in subdivision (a) of Section 11100 to a person or business entity in this state or any other state or who obtains from a source outside of the state any substance specified in subdivision (a) of Section 11100 shall submit an application to, and obtain a permit for the conduct of that business from, the Department of Justice. For any substance added to the list set forth in subdivision (a) of Section 11100 on or after January 1, 2002, the Department of Justice may postpone the effective date of the requirement for a permit for a period not to exceed six months from the listing date of the substance.

(B) An intracompany transfer does not require a permit if the transferor is a permittee. Transfers between company partners or between a company and an analytical laboratory do not require a permit if the transferor is a permittee and a report as to the nature and extent of the transfer is made to the Department of Justice pursuant to Section 11100 or 11100.1.

(C) This paragraph shall not apply to any pharmacist or other authorized person who sells or furnishes a substance upon the prescription of a physician, dentist, podiatrist, or veterinarian; or any analytical research facility that purchases no more than 200 milliliters of a liquid controlled chemical substance or one

kilogram of a solid controlled chemical substance, except in the case of the purchase of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, in which case the facility may purchase no more than nine solid grams.

(D) This paragraph shall not apply to the sale, transfer, furnishing, or receipt of any betadine or povidone solution with an iodine content not exceeding 1 percent in containers of eight ounces or less, or any tincture of iodine not exceeding 2 percent in containers of one ounce or less, that is sold over the counter.

(2) Except as provided in paragraph (3), no permit shall be required of any manufacturer, wholesaler, retailer, or other person or entity for the sale, transfer, furnishing, or obtaining of any product which contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is lawfully sold, transferred, or furnished over the counter without a prescription or by a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations adopted thereunder.

(3) A permit shall be required for the sale, transfer, furnishing, or obtaining of preparations in solid or liquid dosage form containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, unless (A) the transaction involves the sale of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products by retail distributors as defined by this article over the counter and without a prescription, or (B) the transaction is made by a person or business entity exempted from the permitting requirements of this subdivision under paragraph (1).

(b) (1) The department shall provide application forms, which are to be completed under penalty of perjury, in order to obtain information relating to the identity of any applicant applying for a permit, including, but not limited to, the business name of the applicant or the individual name, and if a corporate entity, the names of its board of directors, the business in which the applicant is engaged, the business address of the applicant, a full description of any substance to be sold, transferred, or otherwise furnished or to be obtained, the specific purpose for the use, sale, or transfer of those substances specified in subdivision (a) of Section 11100, the training, experience, or education relating to this use, and any additional information requested by the

department relating to possible grounds for denial as set forth in this section, or by applicable regulations adopted by the department.

(2) The requirement for the specific purpose for the use, sale, or transfer of those substances specified in subdivision (a) of Section 11100 does not require applicants or permittees to reveal their chemical processes that are typically considered trade secrets and proprietary business information.

(c) Applicants and permittees shall authorize the department, or any of its duly authorized representatives, as a condition of being permitted, to make any examination of the books and records of any applicant, permittee, or other person, or visit and inspect the business premises of any applicant or permittee during normal business hours, as deemed necessary to enforce this chapter.

(d) An application may be denied, or a permit may be revoked or suspended, for reasons which include, but are not limited to, the following:

(1) Materially falsifying an application for a permit or an application for the renewal of a permit.

(2) If any individual owner, manager, agent, representative, or employee for the applicant who has direct access, management, or control for any substance listed under subdivision (a) of Section 11100, is or has been convicted of a misdemeanor or felony relating to any of the substances listed under subdivision (a) of Section 11100, any misdemeanor drug-related offense, or any felony under the laws of this state or the United States.

(3) Failure to maintain effective controls against the diversion of precursors to unauthorized persons or entities.

(4) Failure to comply with this article or any regulations of the department adopted thereunder.

(5) Failure to provide the department, or any duly authorized federal or state official, with access to any place for which a permit has been issued, or for which an application for a permit has been submitted, in the course of conducting a site investigation, inspection, or audit; or failure to promptly produce for the official conducting the site investigation, inspection, or audit any book, record, or document requested by the official.

(6) Failure to provide adequate documentation of a legitimate business purpose involving the applicant's or permittee's use of any substance listed in subdivision (a) of Section 11100.

(7) Commission of any act which would demonstrate actual or potential unfitness to hold a permit in light of the public safety and welfare, which act is substantially related to the qualifications, functions, or duties of a permitholder.

(8) If any individual owner, manager, agent, representative, or employee for the applicant who has direct access, management, or control for any substance listed under subdivision (a) of Section 11100, willfully violates or has been convicted of violating, any federal, state, or local criminal statute, rule, or ordinance regulating the manufacture, maintenance, disposal, sale, transfer, or furnishing of any of those substances.

(e) Notwithstanding any other provision of law, an investigation of an individual applicant's qualifications, or the qualifications of an applicant's owner, manager, agent, representative, or employee who has direct access, management, or control of any substance listed under subdivision (a) of Section 11100, for a permit may include review of his or her summary criminal history information pursuant to Sections 11105 and 13300 of the Penal Code, including, but not limited to, records of convictions, regardless of whether those convictions have been expunged pursuant to Section 1203.4 of the Penal Code, and any arrests pending adjudication.

(f) The department may retain jurisdiction of a canceled or expired permit in order to proceed with any investigation or disciplinary action relating to a permittee.

(g) The department may grant permits on forms prescribed by it, which shall be effective for not more than one year from the date of issuance and which shall not be transferable. Applications and permits shall be uniform throughout the state, on forms prescribed by the department.

(h) Each applicant shall pay at the time of filing an application for a permit a fee determined by the department which shall not exceed the application processing costs of the department.

(i) A permit granted pursuant to this article may be renewed one year from the date of issuance, and annually thereafter, following the timely filing of a complete renewal application with all supporting documents, the payment of a permit renewal

fee not to exceed the application processing costs of the department, and a review of the application by the department.

(j) Selling, transferring, or otherwise furnishing or obtaining any substance specified in subdivision (a) of Section 11100 without a permit is a misdemeanor or a felony.

(k) (1) No person under 18 years of age shall be eligible for a permit under this section.

(2) No business for which a permit has been issued shall employ a person under 18 years of age in the capacity of a manager, agent, or representative.

(*l*) (1) An applicant, or an applicant's employees who have direct access, management, or control of any substance listed under subdivision (a) of Section 11100, for an initial permit shall submit with the application one set of 10-print fingerprints for each individual acting in the capacity of an owner, manager, agent, or representative for the applicant, unless the applicant's employees are exempted from this requirement by the Department of Justice. These exemptions may only be obtained upon the written request of the applicant.

(2) In the event of subsequent changes in ownership, management, or employment, the permittee shall notify the department in writing within 15 calendar days of the changes, and shall submit one set of 10-print fingerprints for each individual not previously fingerprinted under this section.

~~SEC. 3. Section 11383.5 is added to the Health and Safety Code, to read:~~

~~11383.5. (a) Any person who possesses one-half pound or more of ephedrine or pseudoephedrine, or any salts, isomers, or salts of isomers of ephedrine or pseudoephedrine; or who possesses one-half pound or more of a substance containing ephedrine or pseudoephedrine, or any salts, isomers, or salts of isomers of ephedrine or pseudoephedrine; or who possesses at the same time one-half pound or more of the substances specified in subparagraphs (A) to (D), inclusive, of paragraph (1) of subdivision (c) of Section 11383, or a combination product thereof, is guilty of a felony and shall be punished by imprisonment in the state prison for two, four, or six years.~~

~~(b) This section shall not apply to drug manufacturers licensed by this state or persons authorized by regulation of the Board of~~

~~Pharmacy to possess those substances or combination of substances, or persons as otherwise authorized by law.~~

~~SEC. 4.~~

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2198 **VERSION: AMENDED MARCH 28, 2006**

AUTHOR: HOUSTON **SPONSOR: MEDICAL BOARD OF CALIFORNIA**

RECOMMENDED POSITION:

SUBJECT: HEALTH CARE: CONTROLLED SUBSTANCES AND DANGEROUS DRUGS

Existing Law:

Existing law establishes the California Intractable Pain Treatment Act and the Pain Patient's Bill of Rights. (B&P 2241.5 and H&S 124960)

This Bill:

1) Defines "clearly excessive" to mean an amount or extent that is without substantial medical basis and is substantially greater than the usual amount of prescribing, administering, or use of the therapeutic modalities. (B&P 725 Amended)

2) Defines "addict" as a person whose actions are characterized by one or more of the following: 1) impaired control over drug use; 2) compulsive use; 3) continued use despite harm and craving. (B&P 22412 and H&S 11156 Amended)

3) Requires an "appropriate prior examination" instead of a good faith prior examination of a patient be conducted prior to prescribing, dispensing, or furnishing dangerous drugs or devices. (B&P 2242.1 Amended)

Comment:

1) Author's Intent. The author's intent is to update the law with regard to pain management.

2) Background. In August 2005, the Medical Board of California (MBC) convened a taskforce to review California law regarding pain management. The review was conducted, in part, to respond to findings in two University of Wisconsin's Pain and Policy Studies Group (group) studies, "Achieving Balance in Federal and State Policy: a Guide to Evaluation" updated in 2004, and "Achieving Balance in State Pain Policy, A Progress Report Card" also updated in 2004. (Excerpts of the studies are attached.) The group gave California a grade of "C" on the group's report card.

The taskforce met several times to discuss and draft proposed legislation to amend California's pain management laws. Board staff, as well as Josh Room (Deputy Attorney General), attended a taskforce meeting in January 2006, to provided comments on the legislative proposal. The initial proposal included draft language to amend B&P 4301(e), Unprofessional Conduct. The amendment would have defined the phrase "clearly excessive" in the context of

unprofessional conduct in furnishing excessive quantities of controlled substances. After some discussion, the taskforce dropped the proposal to amend B&P 4301(e).

The language in AB 2198 is the product of the taskforce meetings and, while the bill does not amend pharmacy law, there is concern that the definition of "clearly excessive" may leak over into B&P 4301.

3) Clearly Excessive. The term "clearly excessive" is undefined in the phrases "clearly excessive prescribing or administering of drugs or treatment" in B&P 725 and "clearly excessive furnishing of controlled substances" in B&P 4301. There is concern that if "clearly excessive" is defined in B&P 725, the definition will be applied to B&P 4301 during disciplinary proceedings. This application might require the board to disprove a "medical or pharmacological basis" for excessive furnishing; this would be a new and substantial burden requiring additional expert testimony and proof from the board. The board may want to suggest that an amendment be offered so that the new definition would only apply to B&P 725, the bill should be amended to specify the definition's application.

3) Previous Legislation. SB 402 (Chapter 839, Statutes of 1997) established the Pain Patient's Bill of Rights and stated the legislative findings and declarations regarding the value of opiate drugs to persons suffering from severe chronic intractable pain. It, among other things, authorized a physician who refuses to prescribe opiate medication for a patient who requests the treatment for severe chronic intractable pain to inform the patient that there are physicians who specialize in the treatment of severe chronic intractable pain with methods that include the use of opiates, and authorized a physician who prescribes opiates to prescribe a dosage deemed medically necessary.

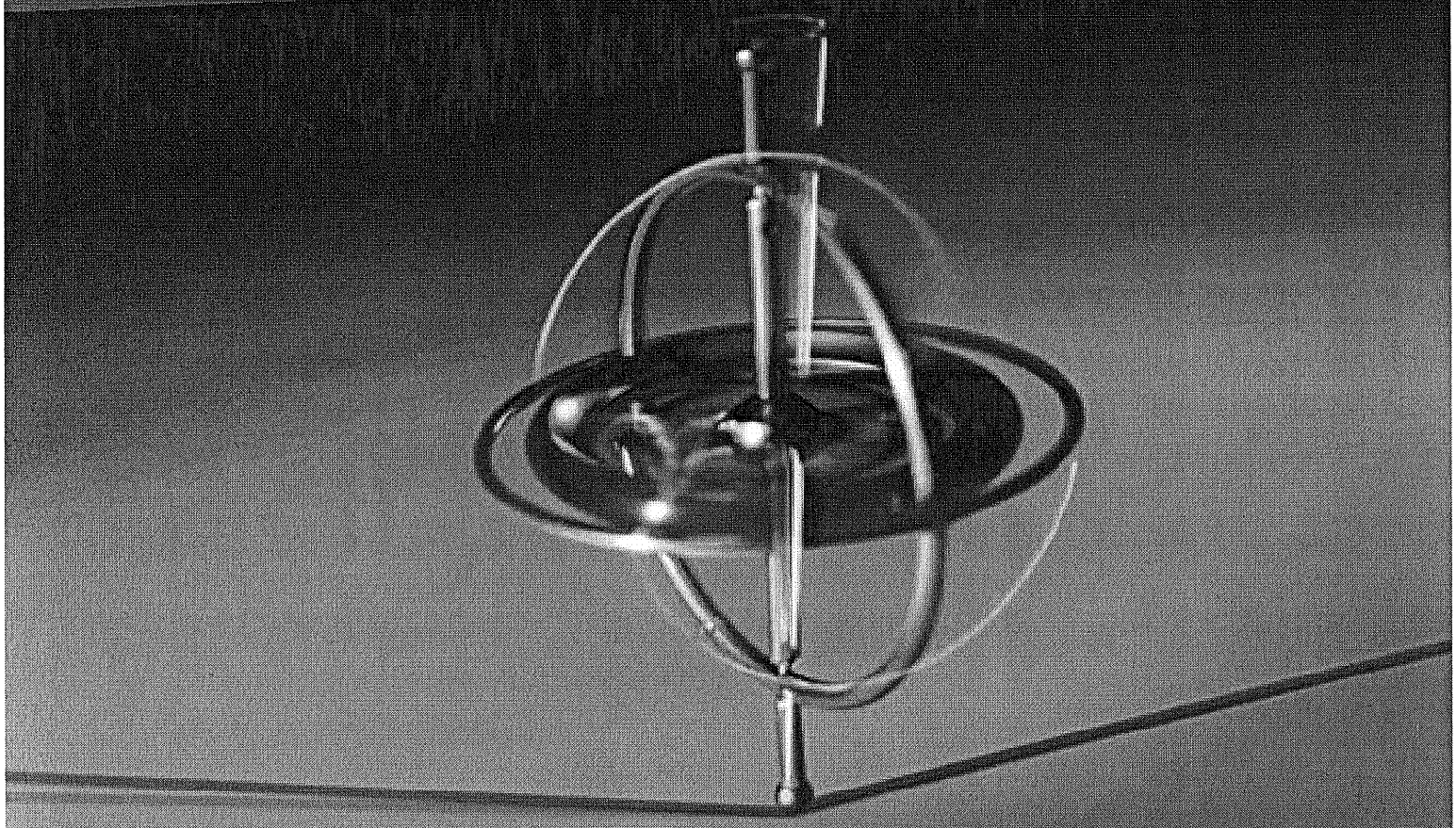
SB 1802 (Chapter 1588, Statutes of 1990) established the California Intractable Pain Treatment Act that authorized a licensed physician to treat intractable pain with narcotic drugs without being subject to Medical Board discipline - subject to specified safeguards to assure that the treatment was medically and therapeutically appropriate.

4) History.

2006

Mar. 30	Re-referred to Com. on B. & P., and then to Com. on HEALTH.
Mar. 29	Re-referred to Com. on HEALTH.
Mar. 28	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 20	Referred to Coms. on HEALTH and B. & P.Feb. 23
Feb. 22	Read first time. To print.

ACHIEVING BALANCE
in Federal & State Pain Policy:
A Guide to Evaluation, Second Edition



Pain & Policy Studies Group
University of Wisconsin
Comprehensive Cancer Center
www.medsch.wisc.edu/painpolicy
Updated February 2004

Supported by:
The Robert Wood Johnson Foundation

Executive Summary

Despite important progress, there continues to be a gap between the possibility and the reality of adequate pain management. Inadequate relief from pain is a serious public health problem in the United States for many underserved populations, including children, the elderly, minorities, nursing home patients, and people with limited financial resources. The pain problem has drawn the attention of a variety of professions, including medicine, pharmacy, nursing, social work, law, and bioethics. Public, professional, and private organizations are developing patient information and professional education; healthcare providers are offering pain management, palliative care, and end-of-life care services.

There are many safe and effective ways to treat pain. However, there is a medical consensus that opioid analgesics are indispensable for a variety of pain types, particularly if pain is severe. Opioid analgesics also have a potential for abuse, so their distribution is strictly regulated under federal and state controlled substances statutes and regulations.

A number of barriers interfere with pain management, in particular with the medical use of opioids. Some of these barriers involve healthcare system issues, such as low institutional priority of pain relief and inadequacies in professional training and clinical practices; others stem from the stigma associated with drug abuse. Impediments in controlled substances and professional practice policies, both real and perceived, can interfere with the prescribing and dispensing of opioid analgesics and, ultimately, patient access to pain relief.

In 2000, the Pain & Policy Studies Group (PPSG) published findings from the first evaluation of federal and state pain policies, entitled *Achieving Balance: A Guide to Evaluation of Federal and State Policies* (*Evaluation Guide 2000*). These findings were the result of a policy analysis based on the Central Principle of *balance*. The principle of *balance* is fundamental to international and national drug control policy and asserts that efforts to prevent abuse of opioid analgesics, while necessary, should not interfere with medical practice and patient care. Balanced policy recognizes the legitimacy of controlled substances prescribing for pain management. The PPSG developed 17 criteria that were used to identify policy provisions with the potential to either enhance or impede patient access to opioid analgesics (called "positive provisions" and "negative provisions" respectively; see Section II for more information). A team of policy analysts used these criteria to assess federal and state policies. The evaluation results were presented for each state, showing each positive and negative provision that was identified.

Since 2000, a number of states have modified their pain policies, making use of a model policy prepared by the Federation of State Medical Boards of the U.S. (Appendix A), as well as suggestions from the *Evaluation Guide 2000*. In order to document the changes that were made during the three-year period, the PPSG updated its policy database through March 2003, evaluated all new or amended policies, and published this, the second edition of the *Evaluation Guide* (*Evaluation Guide 2003*). The methodology for the *Evaluation Guide 2003* is substantially the same as the first. The *Evaluation Guide 2003* presents the results of the second evaluation of federal and state policies, as well as more recent examples of positive policy language and models that can be used to improve state policies even further.

The *Evaluation Guide 2003* is being published concurrently with a *Progress Report Card*, that

quantifies the *Evaluation Guide 2003* results, grades each state's policy environment, and describes the changes in state pain policy between 2000 and 2003.

There can be pitfalls and unintended consequences in reforming pain policy. Changes in policy can advance or retard progress, depending on the content of the policy and the extent of collaboration among stakeholders during policy development. Policy change with no implementation or communication, even when the policy's message is positive, may have little value. Policy change aimed at the health professions and improving practice should be accompanied by a sustained commitment to repeated dissemination and incorporation into effective professional education. A state's policy should not only be balanced, but also *understood* as balanced, and efforts should be made to conform healthcare education to the elements of balanced policy.

The *Evaluation Guide 2003* is not a statement of a "position." Rather, it is the result of systematic policy analysis. While recognizing that states take different approaches to policy formulation, we assert that the overall goal is to improve the regulatory environment for pain management by developing balanced policies. The intent of this effort is to inform state and national policy discussions that lead to more balanced and consistent pain policy. As an increasing number of individuals and organizations examine the policy interface between the "war on drugs" and efforts to relieve pain, it is our hope that they will make use of the *Progress Report Card*, the *Evaluation Guide 2003*, and the many other relevant resources to which links are provided.

The PPSG is grateful to the Robert Wood Johnson Foundation for providing resources to accomplish this project.

CALIFORNIA

POLICIES EVALUATED

Statutes

UNIFORM CONTROLLED SUBSTANCES ACT
Health and Safety Code; Division 10. Uniform Controlled Substances Act

MEDICAL PRACTICE ACT
Business and Professions Code; Division 2. Healing Arts; Chapter 5. Medicine

PHARMACY PRACTICE ACT
Business and Professions Code; Division 2. Healing Arts; Chapter 9. Pharmacy

INTRACTABLE PAIN TREATMENT ACT (*Part of the Medical Practice Act*)
Business and Professions Code; Division 2. Healing Arts; Chapter 5. Medicine; Section 2241.5

HEALTH AND SAFETY CODE
Health and Safety Code; Division 2. Licensing Provisions; Chapter 5. Health Facilities; Article 1. General

PAIN PATIENT'S BILL OF RIGHTS
Health and Safety Code; Division 106. Personal Health Care; Part 4.5

EFFECT ON INTRACTABLE PAIN TREATMENT ACT; BILL OF RIGHTS
Health and Safety Code; Division 106. Personal Health Care; Part 4.5

Regulations

CONTROLLED SUBSTANCES REGULATIONS (*No provisions found*)
Title 16. Professional and Vocational Regulations; Division 17. California State Board of Pharmacy; Article 6. Dangerous Drugs

MEDICAL BOARD REGULATIONS (*No provisions found*)
Title 16. Professional and Vocational Regulations; Division 13. Medical Board of California

PHARMACY BOARD REGULATIONS (*No provisions found*)
Title 16. Professional and Vocational Regulations; Division 17. California State Board of Pharmacy

Other Governmental Policies

Medical Board Policy Statement

California Medical Board. "A Statement by the Medical Board." *Action Report.* Vol. 50, pp. 4-5. July 1994.

Medical Board Guideline

California Medical Board. "Guideline for Prescribing Controlled Substances for Intractable Pain." *Action Report.* Vol. 51, pp. 1 and 8. October 1994. Adopted: May 6, 1994.

Pharmacy Board Policy Statement

California Pharmacy Board. "Dispensing Controlled Substances for Pain." *Health Notes - Pain Management.* Vol. 1, No. 1. 1996.

CALIFORNIA

PROVISIONS THAT MAY ENHANCE PAIN MANAGEMENT

	1	2	3	4	5	6	7	8
Criteria	**Controlled substances are necessary for public health**	**Pain management is part of medical practice**	**Opioids are part of professional practice**	**Encourages pain management**	**Addresses fear of regulatory scrutiny**	**Prescription amount alone does not determine legitimacy**	**Physical dependence or analgesic tolerance are not confused with "addiction"**	**Other provisions that may enhance pain management**
STATUTES								
Controlled Substances Act			●	●	●			●
Medical Practice Act								●
Pharmacy Practice Act[1]								
Intractable Pain Treatment Act		●	●		●			
Health and Safety Code				●				
Pain Patient's Bill of Rights		●						●
Effect on IPTA								●
REGULATIONS								
Controlled Substances[1]								
Medical Board[1]								
Pharmacy Board[1]								
OTHER GOVERNMENTAL POLICIES[2]								
Medical Board Policy Statement		●	●	●	●	●	●	●
Medical Board Guideline		●	●	●	●			
Pharmacy Board Policy Statement			●	●		●	●	

Note: A dot indicates that one or more provisions were identified

[1] No provisions were found in this policy

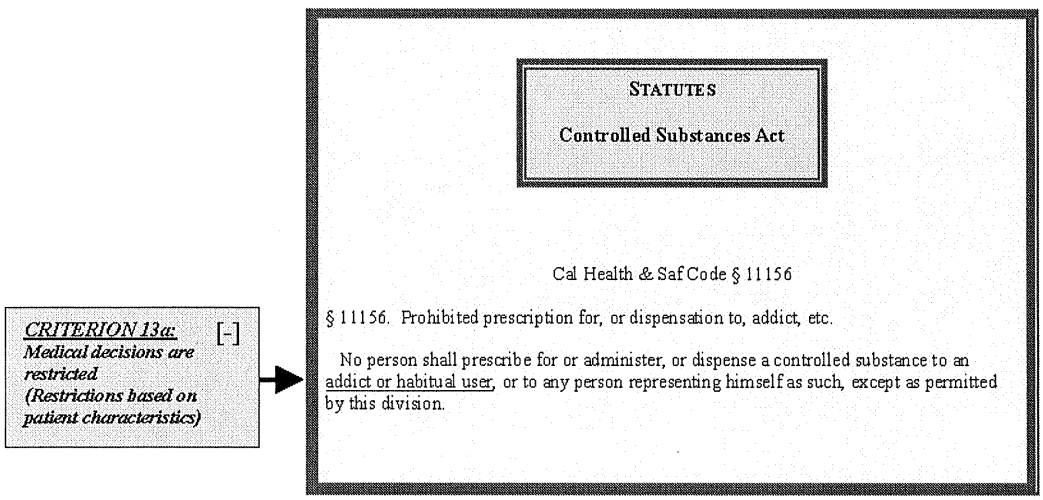
CALIFORNIA

PROVISIONS THAT MAY IMPEDE PAIN MANAGEMENT

	9	10	11	12	13	14	15	16	17
Criteria	**Opioids are a last resort**	**Implies opioids are not part of professional practice**	**Perpetuates belief that opioids hasten death**	**Physical dependence or analgesic tolerance confused with "addiction"**	**Medical decisions are restricted**	**Length of prescription validity is restricted**	**Practitioners are subject to additional prescription requirements**	**Other provisions that may impede pain management**	**Provisions that are ambiguous**
STATUTES									
Controlled Substances Act					●	●	●	●	●
Medical Practice Act					●				●
Pharmacy Practice Act									●
Intractable Pain Treatment Act		●			●				●
Health and Safety Code[1]									
Pain Patient's Bill of Rights[1]									
Effect on IPTA								●	●
REGULATIONS									
Controlled Substances[1]									
Medical Board[1]									
Pharmacy Board[1]									
OTHER GOVERNMENTAL POLICIES									
Medical Board Policy Statement[1]									
Medical Board Guideline					●				●
Pharmacy Board Policy Statement[1]									

Note: A dot indicates that one or more provisions were identified

[1] No provisions were found in this policy


CRITERION 13a: [-]
Medical decisions are restricted
(Restrictions based on patient characteristics)
STATUTES
Controlled Substances Act
Cal Health & Saf Code § 11156
§ 11156. Prohibited prescription for, or dispensation to, addict, etc.
No person shall prescribe for or administer, or dispense a controlled substance to an addict or habitual user, or to any person representing himself as such, except as permitted by this division.

CALIFORNIA

STATUTES

Controlled Substances Act

Cal Health & Saf Code § 11159.2

§ 11159.2. Prescriptions for terminally ill patients

(a) Notwithstanding any other provision of law, a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall not be subject to Section 11164.

(b) (1) The prescription shall be signed and dated by the prescriber and shall contain the name of the person for whom the controlled substance is prescribed, the name and quantity of the controlled substance prescribed, and directions for use. The signature, date, and information required by this paragraph shall be wholly written in ink or indelible pencil in the handwriting of the prescriber.

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed, as provided in paragraph (3) of subdivision (b) of Section 11164, and shall contain the name, address, telephone number, category of professional licensure, and federal controlled substance registration number of the prescriber, as provided in paragraph (2) of subdivision (b) of Section 11164.

(3) The prescription shall also indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."

(c) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (3) of subdivision (b), provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

(d) For purposes of this section, "terminally ill" means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient's illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient's treatment by the physician prescribing a Schedule II controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness.

NOTES: NOTE-

Stats 1998 ch 789 provides:

SECTION 1. (a) The Legislature finds and declares the following:

(1) Although most, if not all, cancer pain can be relieved, a significant number of cancer patients with pain are inadequately treated, and some cancer patients die with severe, unrelieved pain.

(2) The mainstay of cancer pain management is opioid therapy, which therapy utilizes controlled substances classified in Schedule II.

(3) A prescription form for a Schedule II controlled substance is required to be prepared in triplicate, and the original is required to be sent to the Department of Justice.

(4) The Appropriate Prescribing Task Force of the Medical Board of California has recognized that pain is undertreated in California in part due to physicians' concern about undergoing investigation for overprescribing.

(5) Forty-five states in the nation have no requirement for triplicate prescriptions.

(6) Schedule II controlled substances would be prescribed more for the treatment of pain if prescription forms were not required to be sent to the Department of Justice.

(b) It is the intent of the Legislature, by the enactment of this act, to reduce the undertreatment of pain with the appropriate and legal prescribing of Schedule II controlled substances for terminally ill patients in order to relieve their pain and suffering.

. . .

CRITERION 17: [-]
Provisions that are ambiguous

Comment: It is unusual to create an exception to a statutory requirement in order to establish new requirements and a standard of care only for excepted patient groups.

CRITERION 8: [+]
Other provisions that may enhance pain management

Comment: The exemption of these patients from special prescription requirements nevertheless continues those requirements for all other patients.

CRITERION 5: [+]
Addresses fear of regulatory scrutiny

Comment: California legislation acknowledges that the triplicate prescription program is an impediment to the treatment of pain.

CRITERION 3: [+]
Opioids are part of professional practice

CRITERION 4: [+]
Encourages pain management

CALIFORNIA

STATUTES

Controlled Substances Act

Cal Health & Saf Code § 11161

§ 11161. Issuance and nontransferability of prescription blanks; Unlawful possession; Felony violations by practitioners

(a) Prescription blanks shall be issued by the Department of Justice in serially numbered groups of not more than 100 forms each in triplicate unless a practitioner orally, electronically, or in writing requests a larger amount, and shall be furnished to any practitioner authorized to write a prescription for controlled substances classified in Schedule II. The Department of Justice may charge a fee for the prescription blanks sufficient to reimburse the department for the actual costs associated with the preparation, processing, and filing of any forms issued pursuant to this section. The prescription blanks shall not be transferable. Any person possessing a triplicate prescription blank otherwise than as provided in this section is guilty of a misdemeanor. . .

Cal Health & Saf Code § 11165 (2003)

§ 11165. (Operative until July 1, 2008; Repealed January 1, 2009) CURES project for electronic monitoring of prescription drugs

(a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, and the Osteopathic Medical Board of California Contingent Fund, establish the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. CURES shall be implemented as a pilot project, commencing on July 1, 1997, to be administered concurrently with the existing triplicate prescription process, to examine the comparative efficiencies between the two systems.

NOTE-

Stats 1996 ch 738 provides:

SECTION 1. Recognizing that prescription drugs constitute the largest growing source of street drugs in the United States, the Legislature in 1992 approved Senate Concurrent Resolution 74 which convened a Controlled Substance Prescription Advisory Council to evaluate California's current triplicate prescription process for monitoring Schedule II controlled substances. The Legislature supports the council's findings that the ability to closely monitor the prescribing and dispensing of Schedule II controlled substances is essential to effectively control the abuse and diversion of these controlled substances. The Legislature agrees that electronic monitoring appears to offer a more effective method of tracking the prescribing and dispensing of these controlled substances with less intrusion into the legitimate prescribing and dispensing process than experienced by the current triplicate prescription process. However, until an electronic monitoring system is proven effective, the Legislature finds that sufficient cause does not yet exist to eliminate the existing triplicate prescription process.

It is the intent of the Legislature that this electronic monitoring system, the Controlled Substance Utilization Review and Evaluation System (CURES), be capable of providing complete, accurate, and timely data to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. It is the intent of the Legislature that the authorization granted pursuant to this act be used to establish CURES as a three-year pilot project for Schedule II controlled substances, to be administered concurrently with the existing triplicate prescription process, for the purpose of examining comparative efficiencies between the two systems. It is the intent of the Legislature that no new appropriation from the General Fund shall be made to create or maintain CURES.

CRITERION 15: [-]
Additional prescription requirements

CRITERION 8: [+]
Other provisions that may enhance pain management

Comment: A pilot project has been established to study the feasibility of replacing the current triple-copy prescription form with a less burdensome program.

CRITERION 14: [-]
Length of prescription validity is restricted

STATUTES

Controlled Substances Act

Cal Health & Saf Code § 11166

§ 11166. When filling prescription for controlled substance is prohibited

No person shall fill a prescription for a controlled substance classified in Schedule II 14 or more days after the date written on the prescription by the prescriber. No person shall knowingly fill a mutilated or forged or altered prescription for a controlled substance except for the addition of the address of the person for whom the controlled substance is prescribed as provided by paragraph (3) of subdivision (b) of Section 11164.

CRITERION 16: [-]
Other provisions that may impede pain management

Comment: Although institutional review of research is common, state controlled substances statutes governing research with controlled substances are not. Under federal and most state laws, physicians who are licensed to practice medicine and who have a DEA number are authorized to conduct research with the controlled substances which they are authorized to prescribe. California requires an additional approval from the Research Advising Panel, which may place an additional burden on clinical research needed for the development of new pain medications.

STATUTES

Controlled Substances Act

Cal Health & Saf Code § 11213

§ 11213. Lawful obtaining and using substances for research, instruction, or analysis

Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use for such purposes such substances as are defined as controlled substances in this division, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to Sections 11480 and 11481.

Such research, instruction, or analysis shall be carried on only under the auspices of the head of a research project which has been approved by the Research Advisory Panel pursuant to Section 11480 or Section 11481. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.

CALIFORNIA

STATUTES

Medical Practice Act

Cal Bus & Prof Code § 725

§ 725. Excessive prescribing or treatment; Treatment for intractable pain

Repeated acts of clearly excessive prescribing or administering of drugs or treatment, repeated acts of clearly excessive use of diagnostic procedures, or repeated acts of clearly excessive use of diagnostic or treatment facilities as determined by the standard of the community of licensees is unprofessional conduct for a physician and surgeon, dentist, podiatrist, psychologist, physical therapist, chiropractor, or optometrist. However, pursuant to Section 2241.5, no physician and surgeon in compliance with the California Intractable Pain Treatment Act shall be subject to disciplinary action for lawfully prescribing or administering controlled substances in the course of treatment of a person for intractable pain.

Any person who engages in repeated acts of clearly excessive prescribing or administering of drugs or treatment is guilty of a misdemeanor and shall be punished by a fine of not less than one hundred dollars ($100) nor more than six hundred dollars ($600), or by imprisonment for a term of not less than 60 days nor more than 180 days, or by both the fine and imprisonment.

CRITERION 17: [-]
Provisions that are ambiguous

Comment: "Clearly excessive" implies there is a limit, but the limit is not specified.

STATUTES

Medical Practice Act

Cal Bus & Prof Code § 2241

§ 2241. Furnishing drugs to addict

Unless otherwise provided by this section, the prescribing, selling, furnishing, giving away, or administering or offering to prescribe, sell, furnish, give away, or administer any of the drugs or compounds mentioned in Section 2239 to an addict or habitue constitutes unprofessional conduct.

If the drugs or compounds are administered or applied by a licensed physician and surgeon or by a registered nurse acting under his or her instruction and supervision, this section shall not apply to any of the following cases:

(a) Emergency treatment of a patient whose addiction is complicated by the presence of incurable disease, serious accident or injury, or the infirmities attendant upon age.

(b) Treatment of addicts or habitues in state licensed institutions where the patient is kept under restraint and control, or in city or county jails or state prisons.

(c) Treatment of addicts as provided for by Section 11217.5 of the Health and Safety Code.

CRITERION 17: [-]
Provisions that are ambiguous

Comment: It is unusual to create a regulatory exception in order to establish new requirements and a standard of care only for excepted patient groups.

CRITERION 13a: [-]
Medical decisions are restricted (Restrictions based on patient characteristics)

Comment: Despite the exceptions, the status of prescribing opioids for addicts remains unclear.

CRITERION 8: [+]
Other provisions that may enhance pain management

Comment: This exception does not apply to all patients with pain.

STATUTES

Pharmacy Practice Act

Cal Bus & Prof Code § 4301

§ 4301. Unprofessional conduct, procuring license by fraud or misrepresentation, or issuance of license by mistake

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(a) Gross immorality.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

.
.
.

CRITERION 17: [-]
Provisions that are ambiguous

Comment: "Clearly excessive" implies there is a limit, but the limit is not specified.

CALIFORNIA

STATUTES

Intractable Pain Treatment Act

Cal Bus & Prof Code § 2241.5

§ 2241.5. Administration of controlled substances to person experiencing "intractable pain"

(a) Notwithstanding any other provision of law, a physician and surgeon may prescribe or administer controlled substances to a person in the course of the physician and surgeon's treatment of that person for a diagnosed condition causing intractable pain.

(b) "Intractable pain," as used in this section, means a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and surgeon and one or more physicians and surgeons specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain.

(c) No physician and surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain.

(d) This section shall not apply to those persons being treated by the physician and surgeon for chemical dependency because of their use of drugs or controlled substances.

(e) This section shall not authorize a physician and surgeon to prescribe or administer controlled substances to a person the physician and surgeon knows to be using drugs or substances for nontherapeutic purposes.

(f) This section shall not affect the power of the board to deny, revoke, or suspend the license of any physician and surgeon who does any of the following:

(1) Prescribes or administers a controlled substance or treatment that is nontherapeutic in nature or nontherapeutic in the manner the controlled substance or treatment is administered or prescribed or is for a nontherapeutic purpose in a nontherapeutic manner.

(2) Fails to keep complete and accurate records of purchases and disposals of substances listed in the California Controlled Substances Act, or of controlled substances scheduled in, or pursuant to, the federal Comprehensive Drug Abuse Prevention and Control Act of 1970. A physician and surgeon shall keep records of his or her purchases and disposals of these drugs, including the date of purchase, the date and records of the sale or disposal of the drugs by the physician and surgeon, the name and address of the person receiving the drugs, and the reason for the disposal of or the dispensing of the drugs to the person and shall otherwise comply with all state recordkeeping requirements for controlled substances.

(3) Writes false or fictitious prescriptions for controlled substances listed in the California Controlled Substances Act or scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

(4) Prescribes, administers, or dispenses in a manner not consistent with public health and welfare controlled substances listed in the California Controlled Substance Act or scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

(5) Prescribes, administers, or dispenses in violation of either Chapter 4 (commencing with Section 11150) or Chapter 5 (commencing with Section 11210) of Division 10 of the Health and Safety Code or this chapter.

(g) Nothing in this section shall be construed to prohibit the governing body of a hospital from taking disciplinary actions against a physician and surgeon, as authorized pursuant to Sections 809.05, 809.4, and 809.5.

CRITERION 2: [+]
Pain management is part of medical practice

CRITERION 17: [-]
Provisions that are ambiguous

Comment: Does this imply that opioids are a treatment of last resort?

CRITERION 5: [+]
Addresses fear of regulatory scrutiny

CRITERION 3: [+]
Opioids are part of professional practice

CRITERION 10: [-]
Implies opioids are not part of professional practice

CRITERION 13b: [-]
Medical decisions are restricted (Mandated consultation)

CRITERION 13a: [-]
Medical decisions are restricted (Restrictions based on patient characteristics)

STATUTES

Health and Safety Code

Cal Health & Saf Code § 1254.7

§ 1254.7. Pain assessment

(a) It is the intent of the Legislature that pain be assessed and treated promptly, effectively, and for as long as pain persists.

(b) Every health facility licensed pursuant to this chapter shall, as a condition of licensure, include pain as an item to be assessed at the same time as vital signs are taken. The health facility shall ensure that pain assessment is performed in a consistent manner that is appropriate to the patient. The pain assessment shall be noted in the patient's chart in a manner consistent with other vital signs.

CRITERION 4: [+]
Encourages pain management

CALIFORNIA

CRITERION 2: [+]
Pain management is part of medical practice

STATUTES

Pain Patient's Bill of Rights

California Health & Safety Code §124960

§ 124960. Legislative findings and declarations

The Legislature finds and declares all of the following:

(a) The state has a right and duty to control the illegal use of opiate drugs.

(b) Inadequate treatment of acute and chronic pain originating from cancer or noncancerous conditions is a significant health problem.

(c) For some patients, pain management is the single most important treatment a physician can provide.

(d) A patient suffering from severe chronic intractable pain should have access to proper treatment of his or her pain.

(e) Due to the complexity of their problems, many patients suffering from severe chronic intractable pain may require referral to a physician with expertise in the treatment of severe chronic intractable pain. In some cases, severe chronic intractable pain is best treated by a team of clinicians in order to address the associated physical, psychological, social, and vocational issues.

(f) In the hands of knowledgeable, ethical, and experienced pain management practitioners, opiates administered for severe acute and severe chronic intractable pain can be safe.

(g) Opiates can be an accepted treatment for patients in severe chronic intractable pain who have not obtained relief from any other means of treatment.

(h) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities to relieve his or her severe chronic intractable pain.

(i) A physician treating a patient who suffers from severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve severe chronic intractable pain as long as the prescribing is in conformance with the provisions of the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(j) A patient who suffers from severe chronic intractable pain has the option to choose opiate medication for the treatment of the severe chronic intractable pain as long as the prescribing is in conformance with the provisions of the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(k) The patient's physician may refuse to prescribe opiate medication for a patient who requests the treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians who specialize in the treatment of severe chronic intractable pain with methods that include the use of opiates.

CRITERION 8: [+]
Other provisions that may enhance pain management

Comment: This provision recognizes the need for increased communication between healthcare practitioners.

CALIFORNIA

STATUTES

Effect on Intractable Pain Treatment Act; Bill of Rights

California Health & Safety Code §124961

§ 124961. Effect on Intractable Pain Treatment Act; Bill of Rights

Nothing in this section shall be construed to alter any of the provisions set forth in the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code. This section shall be known as the Pain Patient's Bill of Rights.

(a) A patient suffering from severe chronic intractable pain has the option to request or reject the use of any or all modalities in order to relieve his or her severe chronic intractable pain.

(b) A patient who suffers from severe chronic intractable pain has the option to choose opiate medications to relieve severe chronic intractable pain without first having to submit to an invasive medical procedure, which is defined as surgery, destruction of a nerve or other body tissue by manipulation, or the implantation of a drug delivery system or device, as long as the prescribing physician acts in conformance with the provisions of the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(c) The patient's physician may refuse to prescribe opiate medication for the patient who requests a treatment for severe chronic intractable pain. However, that physician shall inform the patient that there are physicians who specialize in the treatment of severe chronic intractable pain with methods that include the use of opiates.

(d) A physician who uses opiate therapy to relieve severe chronic intractable pain may prescribe a dosage deemed medically necessary to relieve severe chronic intractable pain, as long as that prescribing is in conformance with the California Intractable Pain Treatment Act, Section 2241.5 of the Business and Professions Code.

(e) A patient may voluntarily request that his or her physician provide an identifying notice of the prescription for purposes of emergency treatment or law enforcement identification.

(f) Nothing in this section shall do either of the following:

(1) Limit any reporting or disciplinary provisions applicable to licensed physicians and surgeons who violate prescribing practices or other provisions set forth in the Medical Practice Act, Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code, or the regulations adopted thereunder.

(2) Limit the applicability of any federal statute or federal regulation or any of the other statutes or regulations of this state that regulate dangerous drugs or controlled substances.

CRITERION 8: [+]
Other provisions that may enhance pain management

Comment: Sections (a) and (b) recognize the patient's right to choose or refuse different types of treatments.

CRITERION 17: [-]
Provisions that are ambiguous

Comment: It appears that the Pain Patient's Bill of Rights requires that all opiate treatment for patients with "severe chronic intractable pain," must be according to the IPTA, thus requiring an evaluation by a second physician in every case, and excluding certain patient populations. Also, is it legal for a physician to prescribe medically necessary dosages of opioids for patients with severe chronic pain who are not qualified under the IPTA?

CRITERION 17: [-]
Provisions that are ambiguous

Comment: The phrase "severe chronic intractable pain" is used throughout this policy. The intended result of such elaborate and unconventional medical terminology is unclear, but appears to limit the patient population which should be given access to "proper treatment" of pain, including the use of opioids, and which is given the option to request or reject any treatments. What is the effect of this law on patients with pain that is not severe, chronic, or intractable? Is there a greater risk of discipline for a physician who would prescribe opioids to a patient with pain which was not severe, chronic, or intractable?

CRITERION 17: [-]
Provisions that are ambiguous

Comment: This provision may be confusing and even in conflict, when considered in conjunction with provision §124960(g) which states that patients qualify for opiate treatment after "other means of treatment;" in §124961(b), the patient does not have to "submit" to certain treatments.

CRITERION 16: [-]
Other provisions that may impede pain management

Comment: Allowing a physician to refuse to prescribe opioid medications would appear to conflict with criteria that recognize that opioids are necessary for public health and are part of medical practice. Furthermore, how does this qualify as a "Pain Patient's Bill of Rights" if a physician may refuse to provide opioid analgesics to a patient in pain?

Without commenting on the concept of patients' bills of rights, this language would fall short of providing any rights and thus may establish a false expectation for adequate pain management.

CRITERION 4: *Encourages pain management* [+]

CRITERION 2: *Pain management is part of medical practice* [+]

CRITERION 3: *Opioids are part of professional practice* [+]

OTHER GOVERNMENTAL POLICY

Medical Board Statement

A STATEMENT BY THE MEDICAL BOARD

INTRODUCTION

The 1993 report of the Medical Board to the Governor signaled a new beginning in the history of medical regulation in California. An important part of this initiative is implementation of the recommendations made by the Board's Task Force on Appropriate Prescribing, chaired by Jacqueline Trestrail, M.D.

The Task Force was established to look into "malprescribing," one of the fastest growing categories of physician discipline. The Board continues to be concerned that controlled substances are subject to abuse by individuals who seek them for their mood altering and other psychological effects, rather than for legitimate medical purposes.

The Board is also concerned about effective pain management and the appropriate medical use of controlled substances. During the Task Force's public meetings, the members heard testimony that some physicians avoid prescribing controlled substances, including the "triplicate" drugs, for patients with intractable pain for fear of discipline by the Board. The Task Force recommended that the Board take a pro-active approach to emphasize to all California physicians that it supports prescribing of opioid analgesics (narcotics) and other controlled substances when medically indicated for the treatment of pain, including intractable pain. After careful review of this matter, the Board concurs with the following statement.

This statement is consistent with good medical practice, protection of public health and consumer interests, with international treaties, federal and California law, including the California Intractable Pain Treatment Act.

THE PAIN PROBLEM

The Board recognizes that pain, whether due to trauma, surgery, cancer and other diseases, is often undertreated. Minorities, women, children, the elderly and people with HIV/AIDS are at particular risk for under treatment of their pain. Unrelieved pain has a harsh and sometimes disastrous impact on the quality of life of people and their families.

While some progress is being made to improve pain and symptom management, the Board is concerned that a number of factors continue to interfere with effective pain management. These include the low priority of pain management in our health care system, incomplete integration of current knowledge into medical education and clinical practice, lack of knowledge among consumers about pain management, exaggerated fears of opioid side effects and addiction, and fear of legal consequences when controlled substances are used.

PAIN MANAGEMENT SHOULD BE A HIGH PRIORITY IN CALIFORNIA

Principles of quality medical practice dictate that citizens of California who suffer from pain should be able to obtain the relief that is currently available. The Board believes that the appropriate application of current knowledge and treatments would greatly improve the quality of life for many California citizens, and could also reduce the morbidity and the costs that are associated with uncontrolled pain.

In addition to making this statement, the Board will take a number of steps to help make effective pain management a reality in California. The Board has provided information to all state physicians about new clinical practice guidelines for pain management that have been prepared by a panel of experts supported by the Agency for Health Care Policy and Research. The Board also co-sponsored and participated in the March 18, 1994 Pain Management and Appropriate Prescribing Summit in conjunction with the Department of Consumer Affairs on removing impediments to appropriate prescribing of controlled substances for effective pain management. Further, the Board will develop guidelines to help physicians avoid investigation if they appropriately prescribe controlled substances for pain management.

Prescribing Controlled Substances for Pain

THE APPROPRIATE ROLE OF OPIOID ANALGESICS

There are numerous drug and non-drug treatments that are used for the management of pain and other symptoms. The proper treatment of any patient's pain depends upon a careful diagnosis of the etiology of the pain, selection of appropriate and cost-effective treatments, and ongoing evaluation of the results of treatment. Opioid analgesics and other controlled substances are useful for the treatment of pain, and are considered the cornerstone of treatment of acute pain due to trauma, surgery and chronic pain due to progressive diseases such as cancer. Large doses may be necessary to control pain if it is severe. Extended therapy may be necessary if the pain is chronic.

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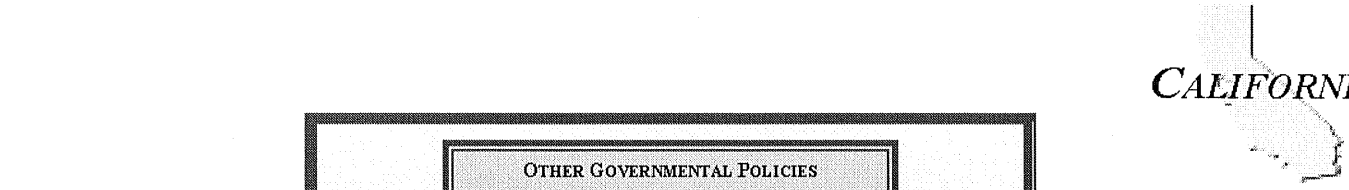


OTHER GOVERNMENTAL POLICIES

Medical Board Statement

(CONTINUED)

The Board recognizes that opioid analgesics can also be useful in the treatment of patients with intractable non-malignant pain especially where efforts to remove the cause of pain or to treat it with other modalities have failed. The pain of such patients may have a number of different etiologies and may require several treatment modalities. In addition, the extent to which pain is associated with physical and psychosocial impairment varies greatly. Therefore, the selection of a patient for a trial of opioid therapy should be based upon a careful assessment of the pain as well as the disability experienced by the patient. Continuation of opioid therapy should be based on the physician's evaluation of the results of treatment, including the degree of pain relief, changes in physical and psychological functioning, and appropriate utilization of health care resources. Physicians should not hesitate to obtain consultation from legitimate practitioners who specialize in pain management.

The Board recommends that physicians pay particular attention to those patients who misuse their prescriptions, particularly when the patient or family have a history of substance abuse that could complicate pain management. The management of pain in such patients requires extra care and monitoring, as well as consultation with medical specialists whose area of expertise is substance abuse or pain management.

The Board believes that addiction should be placed into proper perspective. Physical dependence and tolerance are normal physiologic consequences of extended opioid therapy and are not the same as addiction. Addiction is a behavioral syndrome characterized by psychological dependence and aberrant drug-related behaviors. Addicts compulsively use drugs for non-medical purposes despite harmful effects; a person who is addicted may also be physically dependent or tolerant. Patients with chronic pain should not be considered addicts or habitues merely because they are being treated with opioids.

PAIN MANAGEMENT, CONTROLLED SUBSTANCES AND THE LAW

The laws and regulations of the federal government and the State of California impose special requirements for the prescribing of controlled substances, including requirements as to the form of the prescription document, so as to prevent harm to the public health that is caused when prescription drugs are diverted to non-medical uses. For example, it is illegal to prescribe controlled substances solely to maintain narcotic addiction. However, federal and California law clearly recognize that it is a legitimate medical practice for physicians to prescribe controlled substances for the treatment of pain, including intractable pain.

The Medical Board will work with the Drug Enforcement Administration, the Bureau of Narcotic Enforcement, the Office of the Attorney General, the Board of Pharmacy and its own investigators in an attempt to develop policy and guidelines based on the physician's diagnosis and treatment program rather than amounts of drugs prescribed.

Concerns about regulatory scrutiny should not make physicians who follow appropriate guidelines reluctant to prescribe or administer controlled substances, including Schedule II drugs, for patients with a legitimate medical need for them. A physician is not subject to Board action when prescribing in the regular course of his or her profession to one under the physician's treatment for a pathology or condition and where the prescription is issued after a good faith examination and where there is medical indication for the drug. Good faith prescribing requires an equally good faith history, physical examination and documentation.

The Medical Board may identify a pattern of controlled substance use that merits further examination. A private, courteous and professional inquiry can usually determine whether the physician is in good faith appropriately prescribing for patients, or whether an investigation is necessary. The Board will judge the validity of prescribing based on the physician's diagnosis and treatment of the patient and whether the drugs prescribed by the physician are appropriate for that condition, and will not act on the basis of predetermined numerical limits on dosages or length of drug therapy.

The Board hopes to replace practitioners' perception of inappropriate regulatory scrutiny with recognition of the Board's commitment to enhance the quality of life of patients by improving pain management while, at the same time, preventing the diversion and abuse of controlled substances.

CRITERION 7: [+]
Physical dependence or analgesic tolerance are not confused with "addiction"

CRITERION 5: [+]
Addresses fear of regulatory scrutiny

CRITERION 6: [+]
Prescription amount alone does not determine legitimacy

CRITERION 8: [+]
Other provisions that may enhance pain management

Comment: This provision reflects the principle of Balance, which states that the regulation of controlled substances should not interfere with legitimate medical use.

OTHER GOVERNMENTAL POLICIES

Medical Board Guideline

GUIDELINE FOR PRESCRIBING CONTROLLED SUBSTANCES
FOR INTRACTABLE PAIN

PREAMBLE

On May 6, 1994, the Medical Board of California formally adopted a policy statement entitled "Prescribing controlled substances for pain." (Action Report, July 1994) The statement outlines the Board's proactive approach to improving appropriate prescribing for effective pain management in California, while preventing drug diversion and abuse. The policy statement is the product of a year of research, hearings and discussions. California physicians are encouraged to consult the policy statement and these guidelines.

The Medical Board recognizes that inappropriate prescribing of controlled substances including the opioids can lead to drug abuse and diversion. Inappropriate prescribing can also lead to ineffective management of pain, unnecessary suffering of patients and increased health care costs. The Board recognizes that some physicians do not treat pain properly due to lack of knowledge or concern about pain. Fear of discipline by the Board may also be an impediment to medically appropriate prescribing for pain. This Guideline is intended to encourage effective pain management in California, and help physicians reach a level of comfort about appropriate prescribing by clarifying the principles of professional practice that are endorsed by the Board.

"A HIGH PRIORITY"

The Board strongly urges physicians to view effective pain management as a high priority in all patients, including children and the elderly. Pain should be assessed and treated promptly, effectively and for as long as pain persists. The medical management of pain should be based on up-to-date knowledge about pain, pain assessment and pain treatment. Pain treatment may involve the use of several drug and non-drug treatment modalities, often in combination. For some types of pain the use of drugs is emphasized and should be pursued vigorously; for other types, the use of drugs is better de-emphasized in favor of other therapeutic modalities. Physicians should have sufficient knowledge or consultation to make such judgments for their patients.

Drugs, in particular the opioid analgesics, are considered the cornerstone of treatment for pain associated with trauma, surgery, medical procedures, and cancer. Physicians are referred to the U.S. Agency for Health Care Policy and Research Clinical Practice Guidelines which have been endorsed by the Board as a sound yet flexible approach to the management of these types of pain.

The prescribing of opioid analgesics for other patients with intractable non-cancer pain may also be beneficial, especially when efforts to remove the cause of pain or to treat it with other modalities have been unsuccessful.

Intractable pain is defined by law in California as: "a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts including, but not limited to, evaluation by the attending physician and surgeon and one or more physicians and surgeons specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain." (Section 2241.5(b) California Business and Professions Code)

Physicians who prescribe opioids for intractable pain should not fear disciplinary action from any enforcement or regulatory agency in California if they follow California law (section 2241.5 (c)), which reads, "No physician and surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain." Also, physicians should use sound clinical judgment, and care for their patients according to the following principles of responsible professional practice:

(CONTINUED ON NEXT PAGE)

CRITERION 5: [+]
Addresses fear of regulatory scrutiny

CRITERION 2: [+]
Pain management is part of medical practice

CRITERION 17: [-]
Provisions that are ambiguous

Comment: Does this imply that opioids are a treatment of last resort?

CRITERION 4: [+]
Encourages pain management

CRITERION 3: [+]
Opioids are part of professional practice

CRITERION 13b: [-]
Medical decisions are restricted (Mandated consultation)

OTHER GOVERNMENTAL POLICIES

Medical Board Guideline

NEW, EASY GUIDELINES ON PRESCRIBING

1. HISTORY/PHYSICAL EXAMINATION

A medical history and physical examination must be accomplished. This includes an assessment of the pain, physical and psychological function, substance abuse history, assessment of underlying or coexisting diseases or conditions, and should also include the presence of a recognized medical indication for the use of a controlled substance. Prescribing controlled substances for intractable pain in California, as noted in the definition in the text of the Report, also requires evaluation by one or more specialists.

2. TREATMENT PLAN, OBJECTIVES

The treatment plan should state objectives by which treatment success can be evaluated, such as pain relief and/or improved physical and psychosocial function, and indicate if any further diagnostic evaluations or other treatments are planned. The physician should tailor drug therapy to the individual medical needs of each patient. Several treatment modalities or a rehabilitation program may be necessary if the pain has differing etiologies or is associated with physical and psychosocial impairment.

3. INFORMED CONSENT

The physician should discuss the risks and benefits of the use of controlled substances with the patient or guardian.

4. PERIODIC REVIEW

The physician should periodically review the course of opioid treatment of the patient and any new information about the etiology of the pain. Continuation or modification of opioid therapy depends on the physician's evaluation of progress toward treatment objectives. If the patient has not improved, the physician should assess the appropriateness of continued opioid treatment or trial of other modalities.

5. CONSULTATION

The physician should be willing to refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. In addition, physicians should give special attention to those pain patients who are at risk for misusing their medications including those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse requires extra care, monitoring, documentation and consultation with addiction medicine specialists, and may entail the use of agreements between the provider and the patient that specify the rules for medication use and consequences for misuse.

6. RECORDS

The physician should keep accurate and complete records according to items 1-5 above, including the medical history and physical examination, other evaluations and consultations, treatment plan objectives, informed consent, treatments, medications, agreements with the patient, and periodic reviews.

7. COMPLIANCE WITH CONTROLLED SUBSTANCES LAWS AND REGULATIONS

To prescribe controlled substances, the physician must be appropriately licensed in California, have a valid controlled substances registration and comply with federal and state regulations for issuing controlled substances prescriptions. Physicians are referred to the Physicians Manual of the U.S. Drug Enforcement Administration and the Medical Board's Guidebook to Laws Governing the Practice of Medicine by Physicians and Surgeons for specific rules governing issuance of controlled substances prescriptions.

POSTSCRIPT

Under federal and state law, it is unlawful for a physician to prescribe controlled substances to a patient for other than a legitimate medical purpose (for example, prescribing solely for the maintenance of opioid addiction), or outside of professional practice (for example, prescribing without a medical examination of the patient).

It is lawful to prescribe opioid analgesics in the course of professional practice for the treatment of intractable pain according to federal regulations and California Business and Professions Code Section 2241.5, the California Intractable Pain Treatment Act (CIPTA). However, the CIPTA does not apply to those persons being treated by the physician and surgeon for chemical dependency because of their use of drugs or controlled substances (Section 2241.5(d)), and does not authorize a physician or surgeon to prescribe or administer controlled substances to a person the practitioner knows to be using drugs or substances for nontherapeutic purposes (Section 2241.5(e)).

THE MISSION OF THE MEDICAL BOARD OF CALIFORNIA

The mission of the Medical Board of California is to protect consumers through proper licensing of physicians and surgeons and certain allied health professions and through the vigorous, objective enforcement of the Medical Practice Act.

OTHER GOVERNMENTAL POLICIES

Pharmacy Board Policy Statement

DISPENSING CONTROLLED SUBSTANCES FOR PAIN

INTRODUCTION

Healthcare leaders and patient advocates from throughout California met at the Summit on Effective Pain Management: Removing Impediments to Appropriate Prescribing in Los Angeles in 1994 to discuss the effective management of pain. Summit participants concurred that effective pain management, including the use of controlled substance medications, is essential to the health and welfare of Californians experiencing pain. It was also concluded that inappropriate or undertreatment of pain is serious and wide spread.

In response to these findings, the California State Board of Pharmacy is taking a leadership role in promoting the effective management of pain for the state's citizens. The Board's objectives include educating pharmacists on advances in appropriate pain management and taking active roles in providing this therapy. The Board is working to computerize the triplicate prescription program; is encouraging the timely availability of opioids in different healthcare settings such as hospitals, patient's homes and pharmacies; and is encouraging better knowledge and attitudes of patients, the public and other licensed healthcare professionals in the use of pain medications-all with the goal of positively influencing the care of patients in pain.

CRITERION 4: [+] → ***Encourages pain management***

The Board of Pharmacy must ensure that laws, regulations, policies, and practices promote the availability and use of controlled substance drugs to patients for legitimate pain management. The Board encourages programs to help educate patients, the public, and licensed healthcare professionals about the effective use of medications in the treatment of various types of pain. The Board also recognizes that, with proper assessment, therapeutic planning, and follow up, medications should be available and used when needed.

The pharmacist's role (as educator and manager) in providing drug therapy for patients in pain is extensive. If pharmacists are to provide complete pain management services, they must fulfill their responsibilities to:

1. Facilitate the dispensing of legitimate prescriptions;

2. Understand and learn about the effective uses of all pain medications, especially opioids and other controlled substances, in the management of pain;

3. Carefully explain dosage regimens, and discuss potential side effects of pain medications;

4. Monitor and assess the patient for effective pain therapy outcomes, evaluate compliance, assess for tolerance to opioids, and ensure subsequent dosage adjustments as needed;

5. Obtain, retain, and update appropriate information documenting the course of, and need for, on-going opioid therapy;

6. Encourage patients to talk with their pharmacist about their medications, the benefits and problems;

7. Discuss and allay patients' possible fear of addiction with the use of narcotics where this is a factor;

8. Watch for patients who misuse their prescriptions and be especially aware of a patient or family history of substance abuse that might complicate pain management and act accordingly;

(CONTINUED ON NEXT PAGE)

OTHER GOVERNMENTAL POLICIES

Pharmacy Board Policy Statement

(CONTINUED)

9. Assess the patient for adverse drug reactions from the pain therapy regimen and take action to minimize or eliminate them;

10. Be aware of and recommend non-medication treatments for pain or refer patients for such when appropriate;

11. Evaluate OTC, prescription drugs, and alcohol taken with pain medications for potential drug interactions;

12. Recognize that patients and caregivers are important sources of information in assessing the patient's pain therapy;

13. Act as a liaison between patients and other healthcare providers, ensuring that there is open communication and understanding about the drugs patients are taking to reduce pain; and

14. Optimize pain management so patients can reach their highest level of functioning and quality of life.

ROLE OF OPIOIDS IN PAIN MANAGEMENT

Many patients with cancer or chronic medical conditions experience moderate to severe pain that is often inappropriately treated or undermedicated. Pain can have a negative effect on the patient's health and quality of life resulting in needless suffering, emotional distress, loss of productivity and possibly slower recovery from illness, injury, and disease.

Although there have been significant advances in knowledge about pain and the use of opioids and other medications in pain management, many licensed healthcare professionals prescribe, dispense, or administer these medications suboptimally. There is a misconception by patients, the public, and some licensed healthcare providers that opioids are "bad" drugs because opioids are often associated with drug abuse, addiction, and criminal activity. Studies have shown that opioids used appropriately for pain management have an extremely low potential for abuse.

The Board understands that the ongoing use of opioids for cancer, post-surgical, and chronic pain is not what causes addiction or a patient's desire for higher doses of pain medication. Patients suffering from extreme pain or progression of disease may require increased doses of medication; the appropriate dose is that which is required to adequately treat the pain, even if the dose is higher than usually expected. In addition, with long-term treatment of pain with opioids, patients may develop a tolerance to the drug or a dependence on the drug. These occurrences are considered "normal" and "to be expected" - they should not be confused by the licensed healthcare professional with drug addiction or be mislabeled as "drug seeking."

The Board understands that an important part of effective pain management is ensuring that patients do not have difficulty obtaining adequate medication for pain relief. The Board recognizes that it is the professional responsibility of the pharmacist to recommend that patients in pain receive appropriate, timely, and adequate drug therapy to reduce their pain.

CONCLUSION

Recognition of the utility of opioids and other controlled substance drugs for the treatment of pain resulting from a variety of conditions is well established. The need for regulators and practitioners to understand this use, and to adopt laws, policies, and practices is self-evident if patients are to receive relief from pain which is now medically possible. In addition, pharmacists must understand their role in the on-going monitoring and assessment of patients' pain management. Working cooperatively, the Board of Pharmacy and the profession can ensure that opioids and other controlled substance drugs are used appropriately and effectively.

CRITERION 6: [+]
Prescription amount alone does not determine legitimacy

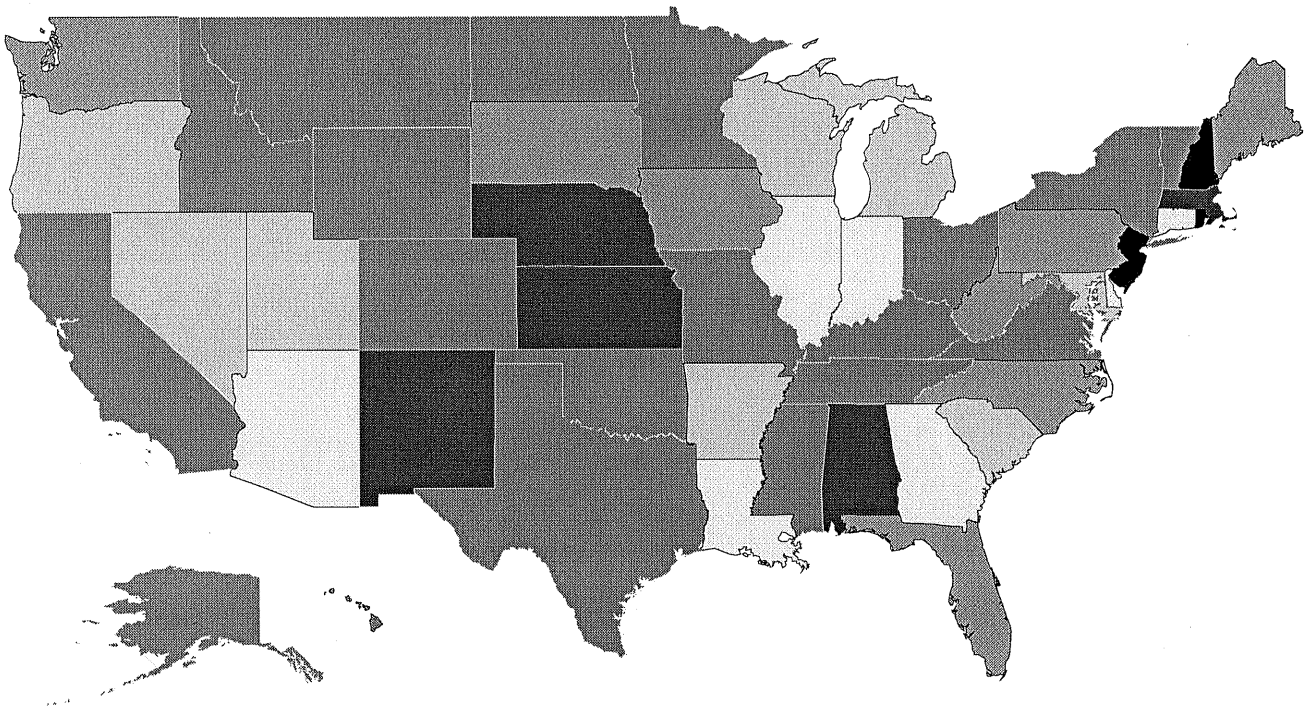
CRITERION 7: [+]
Physical dependence or analgesic tolerance are not confused with "addiction"

CRITERION 3: [+]
Opioids are part of professional practice

MAKING THE GRADE: HOW DO THE STATES RATE?

Grades for 2003

Figure 1:
States' grades for 2003 are presented in Figure 1 and Table 5.



A	B+	B	C+	C	D+	D	F
None	Alabama	Florida	Arkansas	Alaska	Arizona	New Hampshire	None
	Kansas	Iowa	Maryland	California	Connecticut	New Jersey	
	Nebraska	Maine	Michigan	Colorado	Delaware	Rhode Island	
	Massachusetts	North Carolina	Nevada	Idaho	Dist. of Columbia		
	New Mexico	Pennsylvania	Oregon	Kentucky	Georgia		
		South Dakota	South Carolina	Minnesota	Hawaii		
		Washington	Utah	Mississippi	Illinois		
		West Virginia	Wisconsin	Missouri	Indiana		
				Montana	Louisiana		
				New York			
				North Dakota			
				Ohio			
				Oklahoma			
				Tennessee			
				Texas			
				Vermont			
				Virginia			
				Wyoming			

MAKING THE GRADE: HOW DO THE STATES RATE?

Table 5: State Grades for 2003

STATES	2003 GRADES	STATES	2003 GRADES
AL	B+	MT	C
AK	C	NE	B+
AZ	D+	NV	C+
AR	C+	NH	D
CA	C	NJ	D
CO	C	NM	B+
CT	D+	NY	C
DE	D+	NC	B
DC	D+	ND	C
FL	B	OH	C
GA	D+	OK	C
HI	D	OR	C+
ID	C	PA	B
IL	D+	RI	D
IN	D+	SC	C+
IA	B	SD	B
KS	B+	TN	C
KY	C	TX	C
LA	D+	UT	C+
ME	B	VT	C
MD	C+	VA	C
MA	B+	WA	B
MI	C+	WV	B
MN	C	WI	C+
MS	C	WY	C
MO	C		

Description of State Grades for 2003

- 35% of states scored around the average (thereby earning a grade of C), while 41% scored above the average and 24% fell below the average.
- No state received an A or F.
- A few regional patterns emerged: States in the central Midwest (Iowa, Kansas, Nebraska, and South Dakota) received Bs; the neighboring states of Illinois and Indiana, earned grades of D+; western states (California, Colorado, Idaho, Montana, Nevada, Oregon, Utah, and Wyoming) earned grades in the C range; the three states with the largest population (California, New York, and Texas) each earned average grades of C, owing to presence of policies containing many positive provisions but also a substantial number of negative provisions.

Changes from 2000 to 2003

To evaluate changes, either positive or negative, that occurred during the three-year period, 2003 grades were compared with the 2000 grades[h] (see Table 6).

Table 6: State Grades, 2000 and 2003

STATES	2000 GRADES	2003 GRADES	STATES	2000 GRADES	2003 GRADES
AL	B+	B+	MT	C	C
AK	C	C	NE	B+	B+
AZ	D+	D+	NV	D	C+
AR	C+	C+	NH	D	D
CA	C	C	NJ	D	D
CO	C	C	NM	B	B+
CT	D+	D+	NY	C	C
DE	D+	D+	NC	B	B
DC	D+	D+	ND	C	C
FL	C+	B	OH	D+	C
GA	D+	D+	OK	C	C
HI	D	D+	OR	C+	C+
ID	D	C	PA	B	B
IL	D+	D+	RI	D	D
IN	D+	D+	SC	C	C+
IA	D+	B	SD	B	B
KS	B	B+	TN	D+	C
KY	D+	C	TX	C	C
LA	D+	D+	UT	C+	C+
ME	B	B	VT	C	C
MD	C+	C+	VA	C	C
MA	D+	B+	WA	B	B
MI	D+	C+	WV	C+	B
MN	C	C	WI	C	C+
MS	C	C	WY	C	C
MO	D	C			

Although no states received an A or F in either 2000 or 2003, a number of important changes occurred:

- 29% of states received above a C in 2000, increasing to 41% in 2003.
- 20 of 51 states (39%) changed their policies; the policy changes were sufficient in 16 of these states to produce a grade improvement.

[h] 2000 grades were calculated to allow comparison and measure progress; see Method to Assign Grades section.

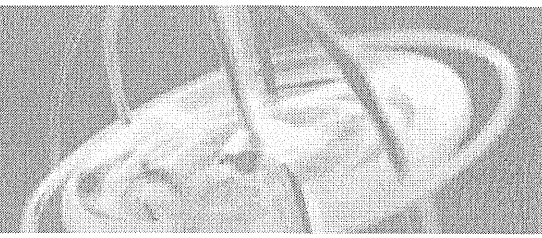
MAKING THE GRADE: HOW DO THE STATES RATE?

- Of the 16 states that improved, Massachusetts had the greatest improvement, moving from a D+ to a B+. This improvement was due to the Federation of State Medical Board's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Model Guidelines)*. States that fully adopt the *Model Guidelines* received the greatest number of positive provisions (7) from a single policy, with no negative provisions:
  - Criterion #2: Pain management is recognized as part of general medical practice,
  - Criterion #3: Medical use of opioids is recognized as legitimate professional practice,
  - Criterion #4: Pain management is encouraged,
  - Criterion #5: Practitioners' concerns about regulatory scrutiny are addressed,
  - Criterion #6: Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing,
  - Criterion #7: Physical dependence or analgesic tolerance are not confused with "addiction," and
  - Criterion #8: Other provisions that may enhance pain management.

Table 7 identifies the states with positive, negative, and no policy change.

Table 7: Grade Change in State Pain Policy Between March 2000 and March 2003

Positive Change (16 states)	No Change (35 states)	
Florida	Alabama	New Hampshire
Hawaii	Alaska	New Jersey
Idaho	Arizona	New York
Iowa	Arkansas	North Carolina
Kansas	California	North Dakota
Kentucky	Colorado	Oklahoma
Massachusetts	Connecticut	Oregon
Michigan	Delaware	Pennsylvania
Missouri	District of Columbia	Rhode Island
Nevada	Georgia	South Dakota
New Mexico	Illinois	Texas
Ohio	Indiana	Utah
South Carolina	Louisiana	Vermont
Tennessee	Maine	Virginia
West Virginia	Maryland	Washington
Wisconsin	Minnesota	Wyoming
	Mississippi	
	Montana	
	Nebraska	



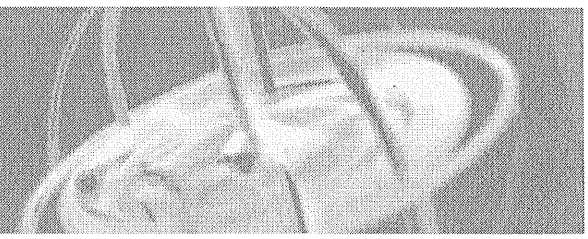
Reasons for the positive changes

The driving force behind the positive policy changes that occurred between 2000 and 2003 was state healthcare regulatory boards that adopted policies encouraging pain management or palliative care.

- Adoption of Model Guidelines: Six states (Kentucky, Massachusetts, Missouri, Nevada, New Mexico, and Texas) adopted healthcare regulatory policies based on the Federation of State Medical Board's *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (Model Guidelines)*. States that fully adopt the *Model Guidelines* received the greatest number of positive provisions (7) from a single policy, with no negative provisions:
  - Criterion #2: Pain management is recognized as part of general medical practice,
  - Criterion #3: Medical use of opioids is recognized as legitimate professional practice,
  - Criterion #4: Pain management is encouraged,
  - Criterion #5: Practitioners' concerns about regulatory scrutiny are addressed,
  - Criterion #6: Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing,
  - Criterion #7: Physical dependence or analgesic tolerance are not confused with "addiction," and
  - Criterion #8: Other provisions that may enhance pain management.

  Twenty-two states have adopted the *Model Guidelines* either in whole or in part.[i]
- Adoption of Pharmacy Board Policies: Iowa adopted a pharmacy board policy statement relating to pain management, which added four positive provisions:
  - Criterion #3: Medical use of opioids is recognized as legitimate professional practice,
  - Criterion #4: Pain management is encouraged,
  - Criterion #5: Practitioners' concerns about regulatory scrutiny are addressed, and
  - Criterion #8: Other provisions that may enhance pain management.
- Adoption of Joint Board Policies: Three states (Kansas, Montana, and West Virginia) approved a joint policy statement relating to the use of controlled substances for the treatment of pain, which was developed collaboratively by several regulatory boards such as medicine, pharmacy, and nursing; collectively, the following positive provisions were added:
  - Criterion #2: Pain management is recognized as part of general medical practice,
  - Criterion #3: Medical use of opioids is recognized as legitimate professional practice,
  - Criterion #4: Pain management is encouraged
  - Criterion #5: Practitioners' concerns about regulatory scrutiny are addressed,
  - Criterion #6: Prescription amount alone is recognized as insufficient to determine the legitimacy of prescribing,
  - Criterion #7: Physical dependence or analgesic tolerance are not confused with "addiction," and
  - Criterion #8: Other provisions that may enhance pain management.

[i] These states are Alabama, Arizona, Florida, Iowa, Kansas, Kentucky, Maine, Massachusetts, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, and West Virginia.



- Adoption of Palliative Care Policies: The Missouri medical board adopted a palliative care guideline to educate physicians about the treatment of terminally-ill patients, adding two positive provisions:
  - Criterion #4: Pain management is encouraged, and
  - Criterion #8: Other provisions that may enhance pain management.

Positive policy change also occurred when states repealed negative provisions.

- Change in Prescription Monitoring Programs: Three states (Hawaii, Idaho, and Michigan) repealed their requirement for a multiple- or single-copy prescription form (Criterion #15) and replaced it with an Electronic Data Transfer system that does not require a special government-issued prescription form. Such a change is thought to eliminate a barrier to pain management because of reluctance to obtain and use the forms and by being a less intrusive method to monitor physicians' prescribing. Only three states (California, New York, and Texas) currently have a multiple- or single-copy prescription form requirement.

- Repeal of Restrictive Prescription Validity Periods: Four states modified overly restrictive prescription validity periods (Criterion #14) from controlled substances statutes and/or regulations:
  - Hawaii eliminated its 3 day period;
  - Michigan eliminated a 5 day period;
  - Wisconsin eliminated a 7 day period; and
  - Idaho extended its validity period from 7 days to 30 days.

  This change eliminates the barrier of an unrealistically short validity period (i.e., the number of days within which the prescription must be dispensed following its issue), which can make it difficult for a patient to obtain medications without having to make sometimes expensive arrangements, especially when travel, slow mail delivery, or other extenuating circumstances exist. Exceeding a prescription's validity period necessitates issuance of a new prescription and a likely return visit to the physician. Seven states have retained a validity period of less than two weeks.[j]

- Repeal of Mandated Consultation Provision: Three states (Iowa, Massachusetts, and Michigan) repealed provisions mandating that physicians always consult with pain specialists when using controlled substances to treat patients with pain (Criterion #13.2). Such provisions typically require a physician treating chronic non-cancer pain with opioids to obtain "...[an] evaluation by the attending physician and one or more physicians specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain..."[57] Although there is no question that physicians should seek consultation when needed, such a requirement may not be necessary for every case, especially if the practitioner is knowledgeable about pain management. In addition, such a requirement does not appear to allow for patients who need immediate treatment. Eleven states continue to mandate consultation under certain circumstances when using opioids to treat patients with pain.[k]

[j] These states are California, Delaware, Illinois, Nevada, Rhode Island, Texas, and Vermont.

[k] These states are Arizona, California, Colorado, Idaho, Mississippi, Nevada, New York, Ohio, Oregon, Rhode Island, and Vermont.

Despite this positive change, a few states added more restrictive provisions.

- Adoption of Hastening Death Provisions: Ohio and Rhode Island added language that perpetuates the misconception that the therapeutic use of opioids to relieve pain in patients at the end of life hastens death (Criterion #11). For example, Rhode Island added statutory language that provides immunity from criminal prosecution to "A licensed health care professional who administers, prescribes or dispenses medications or procedures to relieve another person's pain or discomfort, even if the medication or procedure may hasten or increase the risk of death..."[58] While the intent of the policy as a whole is to encourage pain management, it reinforces an unfounded fear about opioids[59] that can itself contribute to inadequate treatment of pain. Such a provision is now present in 15 states.[l]

- Adoption of Provisions Mandating Opioids as Treatment of Last Resort: Kentucky and Montana added provisions mandating that a physician always document that other treatment measures and drugs have been inadequate or not tolerated before beginning a regimen of controlled substances, suggesting that medical use of opioids is considered, as a matter of policy, a treatment of last resort (Criterion #9). Kentucky's new provision is as follows: "Before beginning a regimen of controlled drugs, the physician must determine, through actual clinical trial or through patient records and history that non-addictive medication regimens have been inadequate or are unacceptable for solid clinical reasons."[60] Currently, 9 states have policies that consider opioids to be a treatment of last resort.[m]

- Adoption of Intractable Pain Treatment Acts: Tennessee adopted an Intractable Pain Treatment Act (IPTA)[61] containing a number of restrictive or ambiguous provisions, such as implying opioids are a treatment of last resort (Criterion #9) and their use is outside legitimate professional practice (Criterion #10), and confusing "addiction" with physical dependence or tolerance (Criterion #12). As of March 2003, 11 states have adopted IPTAs containing restrictive provisions.[n]

[l] These states are Iowa, Indiana, Kansas, Kentucky, Maryland, Michigan, Minnesota, New Hampshire, Ohio, Oklahoma, Rhode Island, South Carolina, South Dakota, Tennessee, and Virginia.

[m] These states are Arizona, Georgia, Kentucky, Louisiana, Mississippi, Montana, Ohio, Tennessee, Virginia, and West Virginia.

[n] These states are California, Colorado, Minnesota, Missouri, North Dakota, Oregon, Rhode Island, Tennessee, Texas, and West Virginia.

AMENDED IN ASSEMBLY MARCH 28, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 2198

Introduced by Assembly Member Houston

February 22, 2006

An act to amend Sections 725, 2241, ~~and 2242~~ *2242, and 2242.1* of, and to repeal and add Section 2241.5 of, the Business and Professions Code, and to amend Section 11156 of the Health and Safety Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 2198, as amended, Houston. Health care: controlled substances and dangerous drugs.

Existing law makes it unprofessional conduct for specified health care providers to engage in repeated acts of clearly excessive prescribing or administering of drugs or treatment, unless the health care provider is a physician and surgeon in compliance with the California Intractable Pain Treatment Act.

This bill would delete the provision prohibiting disciplinary action against a physician and surgeon who is in compliance with the California Intractable Pain Treatment Act. The bill would define "clearly excessive" to mean an amount or extent that is without substantial medical basis and is substantially greater than the usual amount of prescribing, administering, or use of the therapeutic modalities.

Existing law, the Medical Practice Act, provides for the licensing and regulation of physicians and surgeons by the Medical Board of California, and the violation of specified provisions of the act is a crime. The California Intractable Pain Treatment Act, in the Medical

Practice Act, authorizes a physician and surgeon to prescribe or administer controlled substances to a person in the course of treatment for a diagnosed condition causing intractable pain, except in certain circumstances, and prohibits disciplinary action against a physician and surgeon for such action.

This bill would define addict for purposes of these provisions. The bill would delete these provisions and would instead authorize a physician and surgeon to prescribe for, or dispense or administer to, a person for a medical condition drugs or prescription controlled substances for the treatment of pain or a condition causing pain, including intractable pain. The bill would require the physician and surgeon to exercise reasonable care in determining whether a particular patient or condition, or complexity of the patient's treatment, including, but not limited to, a current or recent pattern of drug abuse, requires consultation with, or referral to, a more qualified specialist. A violation of this requirement would be a crime.

Existing law, except as specified, prohibits a person from prescribing or administering or dispensing a controlled substance to an addict or habitual user. Existing law generally makes it unprofessional conduct for a physician and surgeon to prescribe, sell, furnish, give away, or administer certain drugs to an addict or habitué, or to offer to do so, but contains certain exceptions from this provision.

This bill would delete the provision making it unprofessional conduct for a physician and surgeon to prescribe, sell, furnish, give away, or administer certain drugs to an addict or habitué, or to offer to do so~~, and would instead prohibit a physician and surgeon from prescribing, dispensing, or administering prescription drugs or controlled substances to an addict, except for purposes of maintenance on, or detoxification from, prescription drugs or controlled substances or in specified other instances~~. *The bill would authorize a physician and surgeon to prescribe, dispense, or administer prescription drugs, including prescription controlled substances, (1) to an addict under his or her treatment for a condition other than maintenance on, or detoxification from, prescription drugs or controlled substances and (2) under specified conditions to an addict for purposes of maintenance on, or detoxification from, prescription drugs or controlled substances. The bill would also authorize prescription drugs or controlled substances to be administered or applied by a physician and surgeon, or by a registered nurse acting under his or*

her instruction and supervision, in certain circumstances. A violation of this requirement would be a crime.

Existing law makes it unprofessional conduct for a physician and surgeon to prescribe, dispense, or furnish dangerous drugs without a good faith prior examination and medical indication. *Existing law also, with specified exceptions, prohibits a person or entity from prescribing, dispensing, or furnishing, or causing to be prescribed, dispensed, or furnished, dangerous drugs or dangerous devices on the Internet for delivery to a person in California without a good faith prior examination and medical indication.*

This bill would, *for purposes of these provisions,* require an appropriate prior examination instead of a good faith prior examination. The bill would make related legislative findings.

Because this bill would create new crimes, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. The Legislature hereby finds and declares the following:

(a) The investigation and prosecution of pain management cases in California have evolved over the past 15 years.

(b) The Pain Patient's Bill of Rights and the Intractable Pain Treatment Act were created to ensure patients received adequate pain medication and to protect a physician and surgeon from being disciplined solely because of the amounts of controlled substances he or she prescribed or administered.

(c) California recognizes that prescription medication, including controlled substances, can play a critical role in the treatment of pain, and, in and of itself, is an insufficient basis to determine if a physician and surgeon has violated the standard of care in his or her treatment of pain management patients.

(d) California also recognizes that the Intractable Pain Treatment Act may be an impediment to easily accessible pain treatment which can be confusing to both licensees and regulating entities. It can also provide a false sense of security to licensees who may erroneously believe it immunizes them from any actions against their license.

(e) In recognition of the Medical Board of California's consumer protection mandates, and in an attempt to provide better treatment of pain patients, as well as protect the public through the appropriate investigation and prosecution of those who violate the standard of care when treating pain patients, the Legislature recognizes that it is time to reflect upon the current state of pain management to aid both those who treat pain patients, as well as those who investigate and prosecute physicians and surgeons.

SEC. 2. Section 725 of the Business and Professions Code is amended to read:

725. (a) Repeated acts of clearly excessive prescribing, furnishing, dispensing, or administering of drugs or treatment, repeated acts of clearly excessive use of diagnostic procedures, or repeated acts of clearly excessive use of diagnostic or treatment facilities as determined by the standard of the community of licensees is unprofessional conduct for a physician and surgeon, dentist, podiatrist, psychologist, physical therapist, chiropractor, or optometrist.

(b) Any person who engages in repeated acts of clearly excessive prescribing or administering of drugs or treatment is guilty of a misdemeanor and shall be punished by a fine of not less than one hundred dollars ($100) nor more than six hundred dollars ($600), or by imprisonment for a term of not less than 60 days nor more than 180 days, or by both the fine and imprisonment.

(c) For purposes of this section, "clearly excessive" shall mean an amount or extent that is both (1) without substantial medical basis and (2) substantially greater than the usual amount of prescribing, administration, or use of therapeutic modalities.

SEC. 3. Section 2241 of the Business and Professions Code is amended to read:

2241. (a) A physician and surgeon may ~~not~~ prescribe, dispense, or administer prescription drugs, including prescription

controlled substances, to an addict under his or her treatment~~,~~ ~~except as follows:~~ *for a condition other than maintenance on, or detoxification from, prescription drugs or controlled substances.*

~~(1)~~

(b) A physician and surgeon may *only* prescribe, dispense, or administer prescription drugs or prescription controlled substances to an addict for purposes of maintenance on or detoxification from prescription drugs or controlled substances as set forth in ~~Section 11217~~ *subdivision (c) or in Sections 11215, 11217, 11217.5, 11218, 11219, and 11220* of the Health and Safety Code. Nothing in this ~~paragraph~~ *subdivision* shall authorize a physician and surgeon to prescribe, dispense, or administer dangerous drugs or controlled substances to a person he or she knows or reasonably believes is using or will use the drugs or substances for a nonmedical purpose.

~~(2) Drugs or controlled substances may be administered or applied to an addict~~

(c) Notwithstanding subdivision (a), prescription drugs or controlled substances may also be administered or applied by a physician and surgeon, or by a registered nurse acting under his or her instruction and supervision, under the following circumstances:

~~(A)~~

(1) Emergency treatment of a patient whose addiction is complicated by the presence of incurable disease, acute accident, illness, or injury, or the infirmities attendant upon age.

~~(B)~~

(2) Treatment of addicts in state licensed institutions where the patient is kept under restraint and control, or in city or county jails or state prisons.

~~(C)~~

(3) Treatment of addicts as provided for by Section 11217.5 of the Health and Safety Code.

~~(b)~~

(d) For purposes of this section and Section 2241.5, "addict" means a person whose actions are characterized by one or more of the following:

(1) Impaired control over drug use.

(2) Compulsive use.

(3) Continued use despite harm and craving.

SEC. 4. Section 2241.5 of the Business and Professions Code is repealed.

SEC. 5. Section 2241.5 is added to the Business and Professions Code, to read:

2241.5. (a) A physician and surgeon may prescribe for, or dispense or administer to, a person under his or her treatment for a medical condition dangerous drugs or prescription controlled substances for the treatment of pain or a condition causing pain, including, but not limited to, intractable pain.

(b) A physician and surgeon's authority under this section shall be subject to the provisions of Sections *725,* 2234, 2241, 2242, and 2242.1, and Sections 11152, 11153, and 11154 of the Health and Safety Code. Nothing in this section shall authorize a physician and surgeon to prescribe, administer or dispense dangerous drugs or controlled substances to a person he or she knows or reasonably believes is using or will use the drugs or substances for a non-medical purpose.

(c) Any physician and surgeon has the legal authority to treat a patient for pain using dangerous drugs or prescription controlled substances but the prescribing, administering, or dispensing physician and surgeon shall exercise reasonable care in determining whether a particular patient or condition, or complexity of the patient's treatment, including, but not limited to, a current or recent pattern of drug abuse, requires consultation with or referral to a more qualified specialist.

SEC. 6. Section 2242 of the Business and Professions Code is amended to read:

2242. (a) Prescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022 without an appropriate prior examination and a medical indication, constitutes unprofessional conduct.

(b) No licensee shall be found to have committed unprofessional conduct within the meaning of this section if, at the time the drugs were prescribed, dispensed, or furnished, any of the following applies:

(1) The licensee was a designated physician and surgeon or podiatrist serving in the absence of the patient's physician and surgeon or podiatrist, as the case may be, and if the drugs were prescribed, dispensed, or furnished only as necessary to maintain

the patient until the return of his or her practitioner, but in any case no longer than 72 hours.

(2) The licensee transmitted the order for the drugs to a registered nurse or to a licensed vocational nurse in an inpatient facility, and if both of the following conditions exist:

(A) The practitioner had consulted with the registered nurse or licensed vocational nurse who had reviewed the patient's records.

(B) The practitioner was designated as the practitioner to serve in the absence of the patient's physician and surgeon or podiatrist, as the case may be.

(3) The licensee was a designated practitioner serving in the absence of the patient's physician and surgeon or podiatrist, as the case may be, and was in possession of or had utilized the patient's records and ordered the renewal of a medically indicated prescription for an amount not exceeding the original prescription in strength or amount or for more than one refilling.

(4) The licensee was acting in accordance with Section 120582 of the Health and Safety Code.

SEC. 7. Section 2242.1 of the Business and Professions Code is amended to read:

2242.1. (a) No person or entity may prescribe, dispense, or furnish, or cause to be prescribed, dispensed, or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state, without ~~a good faith~~ *an appropriate* prior examination and medical indication ~~therefor~~, except as authorized by Section 2242.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to either a fine of up to twenty-five thousand dollars ($25,000) per occurrence pursuant to a citation issued by the board or a civil penalty of twenty-five thousand dollars ($25,000) per occurrence.

(c) The Attorney General may bring an action to enforce this section and to collect the fines or civil penalties authorized by subdivision (b).

(d) For notifications made on and after January 1, 2002, the Franchise Tax Board, upon notification by the Attorney General or the board of a final judgment in an action brought under this section, shall subtract the amount of the fine or awarded civil

penalties from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Contingent Fund of the Medical Board of California.

(e) If the person or entity that is the subject of an action brought pursuant to this section is not a resident of this state, a violation of this section shall, if applicable, be reported to the person's or entity's appropriate professional licensing authority.

(f) Nothing in this section shall prohibit the board from commencing a disciplinary action against a physician and surgeon pursuant to Section 2242.

~~SEC. 7.~~

SEC. 8. Section 11156 of the Health and Safety Code is amended to read:

11156. (a) No person shall prescribe for or administer, or dispense a controlled substance to an addict~~ or habitual user~~, or to any person representing himself or herself as such, except as permitted by this division.

(b) For purposes of this section, "addict" means a person whose actions are characterized by one or more of the following:

(1) Impaired control over drug use.

(2) Compulsive use.

(3) Continued use despite harm and craving.

~~SEC. 8.~~

SEC. 9. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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AMENDED IN ASSEMBLY APRIL 5, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 2308

Introduced by Assembly Member Plescia

February 22, 2006

~~An act to amend Section 2472 of, and to repeal Section 4190 of, the~~ *An act to amend Sections 2472 and 4190 of the* Business and Professions Code, ~~and~~ to amend Sections ~~1201,~~ 1204, ~~1206, 1214.1, 1242, and 1248.1 of, to add Sections 1200.2 and 1204.2 to, and to repeal Section 1233 of, the Health and Safety Code, relating~~ *1206, 1214.1, 1226, 1226.5, 1233, 1242, and 1248.1 of, and to add Section 1204.2 to, the Health and Safety Code, and to amend Section 139.3 of the Labor Code, relating* to health clinics.

LEGISLATIVE COUNSEL'S DIGEST

AB 2308, as amended, Plescia. Ambulatory surgical centers: licensure.

Existing law, *with certain exceptions,* provides for the licensure and regulation of health facilities and clinics, including specialty clinics, by the State Department of Health Services. Existing law defines a specialty clinic to include a surgical clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. A violation of these provisions is a crime.

This bill would ~~repeal~~ *delete* the definition of a surgical clinic for purposes of various licensure and regulatory requirements, ~~would make various conforming changes, and~~ would ~~require~~, *instead, provide for* the licensure of ambulatory surgical centers, as ~~specified~~ *defined, and would make various conforming changes*. The bill would require a licensed ambulatory surgical center to meet specified

requirements. By creating new crimes, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 2472 of the Business and Professions Code is amended to read:

2472. (a) The certificate to practice podiatric medicine authorizes the holder to practice podiatric medicine.

(b) As used in this chapter, "podiatric medicine" means the diagnosis, medical, surgical, mechanical, manipulative, and electrical treatment of the human foot, including the ankle and tendons that insert into the foot and the nonsurgical treatment of the muscles and tendons of the leg governing the functions of the foot.

(c) A doctor of podiatric medicine may not administer an anesthetic other than local. If an anesthetic other than local is required for any procedure, the anesthetic shall be administered by another licensed health care practitioner who is authorized to administer the required anesthetic within the scope of his or her practice.

(d) (1) A doctor of podiatric medicine who is ankle certified by the board on and after January 1, 1984, may do the following:

(A) Perform surgical treatment of the ankle and tendons at the level of the ankle pursuant to subdivision (e).

(B) Perform services under the direct supervision of a physician and surgeon, as an assistant at surgery, in surgical procedures that are otherwise beyond the scope of practice of a doctor of podiatric medicine.

(C) Perform a partial amputation of the foot no further proximal than the Chopart's joint.

(2) Nothing in this subdivision shall be construed to permit a doctor of podiatric medicine to function as a primary surgeon for any procedure beyond his or her scope of practice.

(e) A doctor of podiatric medicine may perform surgical treatment of the ankle and tendons at the level of the ankle only in the following locations:

(1) A licensed general acute care hospital, as defined in Section 1250 of the Health and Safety Code.

(2) A licensed ambulatory surgical center, as defined in Section 1204 of the Health and Safety Code, if the doctor of podiatric medicine has surgical privileges, including the privilege to perform surgery on the ankle, in a general acute care hospital described in paragraph (1) and meets all the protocols of the ambulatory surgical center.

~~(2)~~

(3) An ambulatory surgical center that is certified to participate in the Medicare Program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act, if the doctor of podiatric medicine has surgical privileges, including the privilege to perform surgery on the ankle, in a general acute care hospital described in paragraph (1) and meets all the protocols of the surgical center.

~~(3)~~

(4) A freestanding physical plant housing outpatient services of a licensed general acute care hospital, as defined in Section 1250 of the Health and Safety Code, if the doctor of podiatric medicine has surgical privileges, including the privilege to perform surgery on the ankle, in a general acute care hospital described in paragraph (1). For purposes of this section, a "freestanding physical plant" means any building that is not physically attached to a building where inpatient services are provided.

~~(4)~~

(5) An outpatient setting accredited pursuant to subdivision (g) of Section 1248.1 of the Health and Safety Code.

(f) A doctor of podiatric medicine shall not perform an admitting history and physical examination of a patient in an acute care hospital where doing so would violate the regulations governing the Medicare program.

(g) A doctor of podiatric medicine licensed under this chapter is a licentiate for purposes of paragraph (2) of subdivision (a) of Section 805, and thus is a health care practitioner subject to the provisions of Section 2290.5 pursuant to subdivision (b) of that section.

~~SEC. 2. Section 4190 of the Business and Professions Code is repealed.~~

~~SEC. 3. Section 1200.2 is added to the Health and Safety Code, to read:~~

~~1200.2. (a) As used in this chapter, "clinic" also means an ambulatory surgical center that is not part of a hospital and which, pursuant to Section 1204.2, primarily provides surgical services that do not exceed an average of four hours of total operating time to patients who do not require overnight hospitalization or who do not pose a significant safety risk according to classifications determined by the American Society of Anesthesiologists and, beginning at a time of postoperative care, remain less than 24 hours.~~

~~(b) An ambulatory surgical center does not include any place or establishment owned or leased and operated as a clinic or office by one or more physicians and surgeons, podiatrists, or dentists in individual or group practice, regardless of the name used publicly to identify the place or establishment, provided, however, that physicians and surgeons, podiatrists, or dentists may, at their option, apply for licensure.~~

~~SEC. 4. Section 1201 of the Health and Safety Code is amended to read:~~

~~1201. "License" means a basic permit to operate a clinic. A license may only be granted to a clinic of a type enumerated in Section 1204, 1204.1, or 1204.2, and the license shall not be transferable. However, the issuance of a license upon a change of ownership shall not of itself constitute a project within the meaning of Section 127170.~~

SEC. 2. Section 4190 of the Business and Professions Code is amended to read:

4190. (a) Notwithstanding any provision of this chapter, ~~a surgical clinic, as defined in~~ *an ambulatory surgical center, licensed pursuant to* paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, *accredited by an accreditation agency pursuant to Section 1248 of the Health and*

Safety Code, or certified to participate in the Medicare Program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act, may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the ~~clinic~~ *center*, as provided in subdivision (b). The ~~clinic~~ *center* shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of seven years for inspection by all properly authorized personnel.

(b) The drug distribution service of ~~a surgical clinic~~ *an ambulatory surgical center* shall be limited to the use of drugs for administration to the patients of the ~~surgical clinic~~ *ambulatory surgical center* and to the dispensing of drugs for the control of pain and nausea for patients of the ~~clinic~~ *center*. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

(c) No ~~surgical clinic~~ *ambulatory surgical center* shall operate without a license issued by the board nor shall it be entitled to the benefits of this section until it has obtained a license from the board. Each license shall be issued to a specific ~~clinic~~ *center* and for a specific location.

~~SEC. 5.~~

SEC. 3. Section 1204 of the Health and Safety Code is amended to read:

1204. Clinics eligible for licensure pursuant to this chapter ~~are primary care clinics, specialty clinics, and ambulatory surgical centers.~~ *are primary care clinics and specialty clinics.*

(a) (1) Only the following defined classes of primary care clinics shall be eligible for licensure:

(A) A "community clinic" means a clinic operated by a tax-exempt nonprofit corporation that is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money, goods, or services. In a community clinic, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. No corporation other than a

nonprofit corporation, exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954 as amended, or a statutory successor thereof, shall operate a community clinic; provided, that the licensee of any community clinic so licensed on the effective date of this section shall not be required to obtain tax-exempt status under either federal or state law in order to be eligible for, or as a condition of, renewal of its license. No natural person or persons shall operate a community clinic.

(B) A "free clinic" means a clinic operated by a tax-exempt, nonprofit corporation supported in whole or in part by voluntary donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money, goods, or services. In a free clinic there shall be no charges directly to the patient for services rendered or for drugs, medicines, appliances, or apparatuses furnished. No corporation other than a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954 as amended, or a statutory successor thereof, shall operate a free clinic; provided, that the licensee of any free clinic so licensed on the effective date of this section shall not be required to obtain tax-exempt status under either federal or state law in order to be eligible for, or as a condition of, renewal of its license. No natural person or persons shall operate a free clinic.

(2) Nothing in this subdivision shall prohibit a community clinic or a free clinic from providing services to patients whose services are reimbursed by third-party payers, or from entering into managed care contracts for services provided to private or public health plan subscribers, as long as the clinic meets the requirements identified in subparagraphs (A) and (B). For purposes of this subdivision, any payments made to a community clinic by a third-party payer, including, but not limited to, a health care service plan, shall not constitute a charge to the patient. This paragraph is a clarification of existing law.

(b) The following types of specialty clinics shall be eligible for licensure as specialty clinics pursuant to this chapter:

(1) An ambulatory surgical center means a clinic that is not part of a hospital and which, pursuant to Section 1204.2, primarily provides surgical services that do not exceed an

average of four hours of total operating time to patients who do not require overnight hospitalization or who do not pose a significant safety risk according to classifications determined by the American Society of Anesthesiologists and, beginning at a time of postoperative care, remain less than 24 hours. An ambulatory surgical center does not include any place or establishment owned or leased and operated as a clinic or office by one or more physicians and surgeons, or dentists in individual or group practice, regardless of the name used publicly to identify the place or establishment, provided, however, that physicians and surgeons or dentists may, at their option, apply for licensure.

~~(1)~~

(2) A "chronic dialysis clinic" means a clinic that provides less than 24-hour care for the treatment of patients with end-stage renal disease, including renal dialysis services.

~~(2)~~

(3) A "rehabilitation clinic" means a clinic that, in addition to providing medical services directly, also provides physical rehabilitation services for patients who remain less than 24 hours. Rehabilitation clinics shall provide at least two of the following rehabilitation services: physical therapy, occupational therapy, social, speech pathology, and audiology services. A rehabilitation clinic does not include the offices of a private physician in individual or group practice.

~~(3)~~

(4) An "alternative birth center" means a clinic that is not part of a hospital and that provides comprehensive perinatal services and delivery care to pregnant women who remain less than 24 hours at the facility.

~~SEC. 6.~~

SEC. 4. Section 1204.2 is added to the Health and Safety Code, to read:

1204.2. (a) Notwithstanding Section 1248, ~~in addition to the primary care clinics and specialty clinics specified in Section 1204, clinics eligible for licensure pursuant to this chapter include ambulatory surgical centers. Nothing in this chapter shall~~ *an ambulatory surgical center described in Section 1204 shall be subject to the requirements of this section. Nothing in this chapter shall* prohibit an ambulatory surgical center from

referring a ~~nonemergency patient to a lower classification facility.~~ *nonemergency patient to a Tier 2 or lower classification facility as determined by the department.*

(b) Failure to comply with this section may be grounds for denial, revocation, or suspension of the license by the department.

(c) The department may accept accreditation by an accreditation agency, as defined in subdivision (d) of Section 1248, as evidence that an ambulatory surgical center demonstrates compliance with, or meets the initial licensing requirements set forth in, this chapter.

(d) The department may contract for outside personnel to perform inspections of ambulatory surgical centers as necessary. The department, when feasible, shall contract with a nonprofit, professional organizations that is approved as an accreditation agency, as defined in subdivision (d) of Section 1248, and has demonstrated the ability to administer the provisions of this chapter.

(e) The department may make inspections and investigations as it deems necessary, to investigate complaints, follow up on adverse survey findings, or conduct periodic validation surveys.

(f) An ambulatory surgical center that is licensed as a clinic pursuant to this section shall meet all of the following requirements:

(1) The governing authority shall consist of one or more persons responsible for the organization and administration of the ambulatory surgical center. The governing authority shall do all of the following:

(A) Adopt policies and procedures for the operation of the ambulatory surgical center to ensure compliance with state laws, regulations, and local ordinances.

(B) Adopt the medical staff by laws.

(C) Grant or deny clinical privileges of physicians and surgeons and other members of the medical staff and delineate, in writing, the clinical privileges of each medical staff member.

(D) Adopt a quality management plan.

(E) Appoint an administrator who shall have authority and responsibility to manage the center.

(2) The administrator shall be responsible to the governing authority and act as a liaison between the governing authority,

medical staff, and facility staff. In addition, the administrator shall be responsible for all of the following:

(A) Developing and implementing written administrative policies and procedures governing all of the following:

(i) Personnel employment, orientation, in-service, staffing, and recordkeeping.

(ii) Patient admissions, rights and responsibilities, grievances, medical treatment, and recordkeeping.

(iii) Advance directives, a term which means a living will, prehospital medical care directive, or health care power of attorney.

(iv) Medications procurement and dispensing.

(v) Contract services.

(vi) Infection control, housekeeping, and maintenance.

(vii) Quality management and recordkeeping.

(viii) Emergency treatment and disaster plan.

(ix) Equipment inspection.

(B) Ensuring that all the policies and procedures are available to all employees in the facility.

(C) Developing and implementing a quality management plan. The purpose of the quality management plan is to monitor and evaluate the provision of all aspects of patient care, including physicians and surgeons and contracted services. The quality management plan shall be in writing and describe the objectives, organization, scope, and process for improving quality of care, which shall include the monitoring activities.

(D) Employing personnel to provide outpatient surgical services. "Outpatient surgical services" means those anesthesia and surgical services provided to a patient in an ambulatory surgical center that do not require planned inpatient care following a surgical procedure.

(E) Ensuring that a pharmacy maintained by the center shall be registered as required by law.

(F) Ensuring that pathology services are provided by a laboratory licensed, or exempt from licensure, as required by law.

(G) Designating, in writing, an individual to be on duty, be in charge, and have access to all areas related to patient care and operation of the physical plant when the administrator is not present.

(H) Posting a list of patient rights in a conspicuous area and making a reasonable effort to ensure that personnel apprise each patient or patient's representative of those rights and making a reasonable effort to ensure that language barriers or physical handicaps do not prevent each patient or patient's representative from becoming aware of those rights. "Patient's representative" means either a person acting on behalf of the patient with written consent of the patient or the patient's parent, legal guardian, or surrogate.

(I) Ensuring that personnel are employed to meet the needs of patients and that job descriptions that define qualifications, duties, and responsibilities are established for all personnel.

(J) Requiring personnel, prior to being employed and annually thereafter, to submit either one of the following as evidence of freedom from pulmonary tuberculosis:

(i) A report of a negative Mantoux skin test taken within six months of submitting the report.

(ii) A written statement from a physician stating that, upon an evaluation of a positive Mantoux skin test taken within six months of submitting the physician's statement or a history of a positive Mantoux skin test, the individual was found to be free from tuberculosis.

(K) Providing orientation to each employee within the first week of employment. Orientation shall be specific to the position held by the employee.

(L) Employing a registered nurse as the director of nursing who shall be responsible for the management and supervision of nursing services, including all of the following:

(i) Developing and implementing written nursing and patient care policies and procedures, including medications administration, storage, and disposal.

(ii) Ensuring that the facility is staffed based on the number of patients and their health care needs.

(iii) Participating in quality management activities.

(iv) Appointing a registered nurse, in writing, to act in the absence of the director of nursing.

(M) Maintaining a record of quality management activities and ensuring that any conclusions and recommendations on findings of quality management activities are reported to the governing authority.

(N) Ensuring there is a current listing of all surgical procedures offered by the center and maintaining a chronological register of all surgical procedures performed.

(O) Ensuring that a roster of medical staff that have surgical or anesthesia privileges at the center is available to the center staff, specifying the privileges and limitations of each person on the roster.

(P) Ensuring that a medical record is established and maintained for each patient. Medical and facility staff shall sign with surnames and date their entries in a patient's medical record. Staff shall release medical record information only after receiving the patient's or patient representative's written consent, or as otherwise required or permitted by law. The medical record shall contain all of the following:

(i) Name and address of patient and patient's representative.

(ii) Documentation of advance directives.

(iii) Admitting diagnosis.

(iv) Medical history and physical examination.

(v) Laboratory and radiology reports.

(vi) Consent forms.

(vii) Physician orders and notations.

(viii) Surgeon's operative report.

(ix) Anesthesia report.

(x) Nursing care notations.

(xi) Medications and treatments administered.

(xii) Written acknowledgment of receipt of discharge instructions by the patient or patient's representative.

(Q) Ensuring that the medical record of discharged patient is completed within 30 days of the discharge.

(R) Ensuring that the medical records are maintained for a period of seven years. Medical records shall be retained onsite at the center, or retrievable by center staff within two hours of a request, for a period of one year from a patient's discharge.

(S) Ensuring that written infection control policies and procedures are established and implemented for the surveillance, control, and prevention of infection. The policies and procedures shall include all of the following:

(i) Sterilization methods.

(ii) Storage, maintenance, and distribution of sterile supplies and equipment.

(iii) Disposal of waste, including blood, body tissue, and fluid.

(T) Ensuring that housekeeping and maintenance services are provided to maintain a safe and sanitary environment.

(U) Ensuring that equipment is operational, inspected, and maintained in accordance with the center's policies and procedures. These policies and procedures shall address all of the following:

(i) Testing, calibrating, servicing, or repairing of equipment to ensure that the equipment is free from fire and electrical hazards.

(ii) Maintaining records documenting service and calibration information.

(iii) The use, maintenance, and storage of oxygen and other flammable gases in accordance with applicable law.

(iv) The use and maintenance of electrical equipment in accordance with applicable law.

(V) Ensuring that employees who provide direct patient care shall:

(i) Be 18 years of age or older.

(ii) Be certified in cardiopulmonary resuscitation within the first month of employment, and maintain current certification thereafter.

(iii) Attend six hours of in-service education per year, which is exclusive of orientation, and cardiopulmonary resuscitation and which relates to the purposes and function of an ambulatory surgical center.

(W) Ensuring that personnel records are maintained, including the application for employment, verification of training, certification, or licensure, initial proof of freedom from tuberculosis and annual verification statement thereafter, and orientation and in-service training records.

(X) Ensuring the development of a written disaster plan of operation with procedures to be followed in the event of a fire or threat to patient safety and shall ensure that an emergency evacuation route is posted in every room where patients may be present, except restrooms.

(Y) Ensuring all of the following with respect to emergency preparation:

(i) Fire drills are conducted every three months, and all staff members on duty participate.

(ii) Records of the drills include the date, time, and critique of the drills.

(iii) Records of the drills are maintained for one year.

(3) A registered nurse shall function as a circulating nurse during each surgical procedure. A registered nurse shall be present in the recovery room whenever patients are in the recovery room. A registered nurse shall be in the facility until all patients are discharged. A registered nurse shall ensure that the patient or patient's representative acknowledges, in writing, the physician's written discharge instructions.

(4) The individual responsible for performing the operative procedure shall complete an operative report and any necessary discharge instructions according to medical staff bylaws and ambulatory surgical center policies and procedures. The individual responsible for the administration of anesthesia shall complete an anesthesia report and any necessary discharge instructions according to medical staff bylaws and center policies and procedures.

(5) A licensed physician and surgeon or licensed health care professional shall remain on the premises until all patients are discharged from the recovery room pursuant to subdivision (b) of Section 1248.15.

(6) If an ambulatory surgical center ceases operation, the governing authority shall ensure the preservation of records and notify the department, in writing, of the location of the records.

(7) The medical staff shall have responsibility for all of the following:

(A) Approval of bylaws for the conduct of medical staff activities.

(B) Conducting medical peer review and submitting recommendations to the governing authority for approval.

(C) Establishing written policies and procedures that define the extent of emergency treatment to be performed in the center, including cardiopulmonary resuscitation procedures and provisions for the emergency transfer of a patient.

(8) A medical staff physician shall admit patients to the facility who do not require overnight hospitalization or who do not pose a significant safety risk according to classifications determined by the American Society of Anesthesiologists and, beginning at a time of postoperative care, remain less than 24

hours and who do not, on average, require more than four hours of total operating time.

(9) Within 30 days prior to admission, a medical staff member shall complete a medical history and physical examination of the patient. The individual responsible for performing the operative procedure shall document the preoperative diagnosis and the procedure to be performed. The nursing staff shall ensure that all of the following documents are in the patient's medical record prior to surgery:

(A) A medical history and results of a current physical examination.

(B) A preoperative diagnosis and the results of any laboratory tests or procedures relative to the surgery and the condition of the patient.

(C) Validation of informed consent by the patient or patient's representative for the surgical procedure and care of the patient.

(D) Physicians orders.

(10) Staff shall provide emergency treatment according to the center's policies and procedures.

(11) The ambulatory surgical center shall pass an initial inspection for fire safety by the fire authority having jurisdiction.

(12) The ambulatory surgical center shall ensure that there shall be two recovery beds for each operating room, for up to four operating rooms, whenever general anesthesia is administered. One additional recovery bed shall be required for each additional operating room.

(13) Recovery beds or gurneys shall be located in a space that provides for a minimum of 70 square feet per bed, allowing three feet or more between beds and between the sides of a bed and the wall.

(14) The ambulatory surgical center may provide recliner chairs in the recovery room area for patients who have not received general anesthesia.

(15) The surgical center shall ensure that the following shall be available in the surgical suite:

(A) Oxygen and the means of administration.

(B) Mechanical ventilatory assistance equipment, including airways.

(C) Manual breathing bag, and suction apparatus.

(D) Cardiac monitor, defibrillator, and cardiopulmonary resuscitation drugs as determined by the facility's policies and procedures.

(E) Noninvasive blood pressure monitor.

(F) Oxygen saturation monitor.

~~(G) Temperature monitor.~~

~~(H) End-tidal CO_2.~~

(G) Temperature monitor and an end-tidal CO_2 when general anesthesia is administered.

~~SEC. 7.~~

SEC. 5. Section 1206 of the Health and Safety Code is amended to read:

1206. This chapter does not apply to the following:

~~(a) Except with respect to specialty clinics specified in paragraph (1) of subdivision (b) of Section 1204, any place or~~

(a) Except with respect to the option provided with regard to ambulatory surgical clinics described in paragraph (1) of subdivision (b) of Section 1204 and further, with respect to chronic dialysis clinics described in paragraph (2) of subdivision (b) of Section 1204, any place or establishment owned or leased and operated as a clinic or office by one or more licensed health care practitioners and used as an office for the practice of their profession, within the scope of their license, regardless of the name used publicly to identify the place or establishment.

(b) Any clinic directly conducted, maintained, or operated by the United States or by any of its departments, officers, or agencies, and any primary care clinic specified in subdivision (a) of Section 1204 that is directly conducted, maintained, or operated by this state or by any of its political subdivisions or districts, or by any city. Nothing in this subdivision precludes the state department from adopting regulations that utilize clinic licensing standards as eligibility criteria for participation in programs funded wholly or partially under Title XVIII or XIX of the federal Social Security Act.

(c) Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1601 of Title 25 of the United States Code, that is located on land recognized as tribal land by the federal government.

(d) Clinics conducted, operated, or maintained as outpatient departments of hospitals.

(e) Any facility licensed as a health facility under Chapter 2 (commencing with Section 1250).

(f) Any freestanding clinical or pathological laboratory licensed under Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code.

(g) A clinic operated by, or affiliated with, any institution of learning that teaches a recognized healing art and is approved by the state board or commission vested with responsibility for regulation of the practice of that healing art.

(h) A clinic that is operated by a primary care community or free clinic and that is operated on separate premises from the licensed clinic and is only open for limited services of no more than 20 hours a week. An intermittent clinic as described in this subdivision shall, however, meet all other requirements of law, including administrative regulations and requirements, pertaining to fire and life safety.

(i) The offices of physicians in group practice who provide a preponderance of their services to members of a comprehensive group practice prepayment health care service plan subject to Chapter 2.2 (commencing with Section 1340).

(j) Student health centers operated by public institutions of higher education.

(k) Nonprofit speech and hearing centers, as defined in Section 1201.5. Any nonprofit speech and hearing clinic desiring an exemption under this subdivision shall make application therefor to the director, who shall grant the exemption to any facility meeting the criteria of Section 1201.5. Notwithstanding the licensure exemption contained in this subdivision, a nonprofit speech and hearing center shall be deemed to be an organized outpatient clinic for purposes of qualifying for reimbursement as a rehabilitation center under the Medi-Cal Act (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code).

(*l*) A clinic operated by a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, that conducts medical research and health education and provides health care to its patients

through a group of 40 or more physicians and surgeons, who are independent contractors representing not less than 10 board-certified specialties, and not less than two-thirds of whom practice on a full-time basis at the clinic.

(m) Any clinic, limited to in vivo diagnostic services by magnetic resonance imaging functions or radiological services under the direct and immediate supervision of a physician and surgeon who is licensed to practice in California. This shall not be construed to permit cardiac catheterization or any treatment modality in these clinics.

(n) A clinic operated by an employer or jointly by two or more employers for their employees only, or by a group of employees, or jointly by employees and employers, without profit to the operators thereof or to any other person, for the prevention and treatment of accidental injuries to, and the care of the health of, the employees comprising the group.

(o) A community mental health center, as defined in Section 5601.5 of the Welfare and Institutions Code.

(p) (1) A clinic operated by a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, as an entity organized and operated exclusively for scientific and charitable purposes and that satisfied all of the following requirements on or before January 1, 2005:

(A) Commenced conducting medical research on or before January 1, 1982, and continues to conduct medical research.

(B) Conducted research in, among other areas, prostatic cancer, cardiovascular disease, electronic neural prosthetic devices, biological effects and medical uses of lasers, and human magnetic resonance imaging and spectroscopy.

(C) Sponsored publication of at least 200 medical research articles in peer-reviewed publications.

(D) Received grants and contracts from the National Institutes of Health.

(E) Held and licensed patents on medical technology.

(F) Received charitable contributions and bequests totaling at least five million dollars ($5,000,000).

(G) Provides health care services to patients only:

(i) In conjunction with research being conducted on procedures or applications not approved or only partially approved for payment (I) under the Medicare program pursuant to Section 1359y(a)(1)(A) of Title 42 of the United States Code, or (II) by a health care service plan registered under Chapter 2.2 (commencing with Section 1340), or a disability insurer regulated under Chapter 1 (commencing with Section 10110) of Part 2 of Division 2 of the Insurance Code; provided that services may be provided by the clinic for an additional period of up to three years following the approvals, but only to the extent necessary to maintain clinical expertise in the procedure or application for purposes of actively providing training in the procedure or application for physicians and surgeons unrelated to the clinic.

(ii) Through physicians and surgeons who, in the aggregate, devote no more than 30 percent of their professional time for the entity operating the clinic, on an annual basis, to direct patient care activities for which charges for professional services are paid.

(H) Makes available to the public the general results of its research activities on at least an annual basis, subject to good faith protection of proprietary rights in its intellectual property.

(I) Is a freestanding clinic, whose operations under this subdivision are not conducted in conjunction with any affiliated or associated health clinic or facility defined under this division, except a clinic exempt from licensure under subdivision (m). For purposes of this subparagraph, a freestanding clinic is defined as "affiliated" only if it directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, a clinic or health facility defined under this division, except a clinic exempt from licensure under subdivision (m). For purposes of this subparagraph, a freestanding clinic is defined as "associated" only if more than 20 percent of the directors or trustees of the clinic are also the directors or trustees of any individual clinic or health facility defined under this division, except a clinic exempt from licensure under subdivision (m). Any activity by a clinic under this subdivision in connection with an affiliated or associated entity shall fully comply with the requirements of this subdivision. This subparagraph shall not

apply to agreements between a clinic and any entity for purposes of coordinating medical research.

(2) By January 1, 2007, and every five years thereafter, the Legislature shall receive a report from each clinic meeting the criteria of this subdivision and any other interested party concerning the operation of the clinic's activities. The report shall include, but not be limited to, an evaluation of how the clinic impacted competition in the relevant health care market, and a detailed description of the clinic's research results and the level of acceptance by the payer community of the procedures performed at the clinic. The report shall also include a description of procedures performed both in clinics governed by this subdivision and those performed in other settings. The cost of preparing the reports shall be borne by the clinics that are required to submit them to the Legislature pursuant to this paragraph.

~~SEC. 8.~~

SEC. 6. Section 1214.1 of the Health and Safety Code is amended to read:

1214.1. Notwithstanding Section 1214, each application for *an ambulatory surgical clinic or* a chronic dialysis clinic under this chapter for an initial license, renewal license, license upon change of ownership, or special permit shall be accompanied by an annual fee of three hundred dollars ($300) plus an amount equal to 0.0003 times the clinic's operating cost for the last completed fiscal year.

~~SEC. 9. Section 1233 of the Health and Safety Code is repealed.~~

SEC. 7. Section 1226 of the Health and Safety Code is amended to read:

1226. (a) The regulations shall prescribe the kinds of services which may be provided by clinics in each category of licensure and shall prescribe minimum standards of adequacy, safety, and sanitation of the physical plant and equipment, minimum standards for staffing with duly qualified personnel, and minimum standards for providing the services offered. These minimum standards shall be based on the type of facility, the needs of the patients served, and the types and levels of services provided.

(b) The Office of Statewide Health Planning and Development, in consultation with the Community Clinics Advisory Committee, shall prescribe minimum construction standards of adequacy and safety for the physical plant of clinics as found in the California Building Standards Code.

(c) A city or county, as applicable, shall have plan review and building inspection responsibilities for the construction or alteration of buildings described in paragraph (1) and paragraph (2) of subdivision (b) of Section 1204 and shall apply the provisions of the latest edition of the California Building Standards Code in conducting these plan review responsibilities. For these buildings, construction and alteration shall include conversion of a building to a purpose specified in paragraphs (1) and (2) of subdivision (b) of Section 1204.

Upon the initial submittal to a city or county by the governing authority or owner of these clinics for plan review and building inspection services, the city or county shall reply in writing to the clinic whether or not the plan review by the city or county will include a certification as to whether or not the clinic project submitted for plan review meets the standards as propounded by the office in the California Building Standards Code.

If the city or county indicates that its review will include this certification it shall do all of the following:

(1) Apply the applicable clinic provisions of the latest edition of the California Building Standards Code.

(2) Certify in writing, to the applicant within 30 days of completion of construction whether or not these standards have been met.

(d) If upon initial submittal, the city or county indicates that its plan review will not include this certification, the governing authority or owner of the clinic shall submit the plans to the Office of Statewide Health Planning and Development who shall review the plans for certification whether or not the clinic project meets the standards, as propounded by the office in California Building Standards Code.

(e) When the office performs review for certification, the office shall charge a fee in an amount that does not exceed its actual costs.

(f) The office of the State Fire Marshal shall prescribe minimum safety standards for fire and life safety in ~~surgical clinics~~ *ambulatory surgical centers*.

(g) Notwithstanding subdivision (c), the governing authority or owner of a clinic may request the office to perform plan review services for buildings described in subdivision (c). If the office agrees to perform these services, after consultation with the local building official, the office shall charge an amount not to exceed its actual costs. The construction or alteration of these buildings shall conform to the applicable provisions of the latest edition of the California Building Standards Code for purposes of the plan review by the office pursuant to this subdivision.

(h) Regulations adopted pursuant to this chapter establishing standards for laboratory services shall not be applicable to any clinic that operates a clinical laboratory licensed pursuant to Section 1265 of the Business and Professions Code.

SEC. 8. Section 1226.5 of the Health and Safety Code is amended to read:

1226.5. (a) It is the intent of the Legislature to establish seismic safety standards for facilities licensed as ~~surgical clinics~~ *ambulatory surgical centers* pursuant to this chapter, and for facilities certified for participation in the federal Medicare program as ambulatory surgical centers, which accommodate surgical patients under general anesthesia, but are not required to remain open and usable after an earthquake to accommodate emergency patients.

(b) A facility described in subdivision (a) which, after January 1, 1991, anchors fixed medical equipment to the floor or roof of the facility with a gross operating weight of more than 400 pounds or anchors fixed medical equipment to the walls or ceiling with a gross operating weight of more than 20 pounds shall retain the services of an architect licensed in California, a structural engineer licensed in California, or a civil engineer registered in California to assure that the equipment is anchored in such a manner to meet the requirements of an occupancy importance factor of 1.00, as set forth in Title 24 of the California Code of Regulations.

(c) A facility described in subdivision (a) which retains the services of an architect or engineer for the anchorage of fixed medical equipment shall keep available for inspection by the

department for a period of five years following the installation, a current written certification from the architect or engineer that the equipment is mounted in accordance with the applicable requirements.

SEC. 9. Section 1233 of the Health and Safety Code is amended to read:

1233. ~~A surgical clinic~~ *An ambulatory surgical center* may restrict use of its facilities to members of the medical staff of the ~~surgical clinic~~ *ambulatory surgical center* and other physicians and surgeons approved by the medical staff to practice at the ~~clinic~~ *center*.

SEC. 10. Section 1242 of the Health and Safety Code is amended to read:

1242. The director may temporarily suspend any license issued to a specialty clinic or special permit prior to any hearing, when in his opinion such action is necessary to protect the public welfare. The director shall notify the licensee or holder of a special permit of the temporary suspension and the effective date thereof, and at the same time shall serve such provider with an accusation. Upon receipt of a notice of defense by the licensee or holder of a special permit, the director shall set the matter for hearing within 30 days after receipt of such notice. The temporary suspension shall remain in effect until the time when the hearing is completed and the director has made a final determination on the merits; provided, however, that the temporary suspension shall be deemed vacated if the director fails to make a final determination on the merits within 60 days after the original hearing has been completed.

If the provisions of this chapter or the rules or regulations promulgated by the director are violated by a licensed *ambulatory surgical center or* chronic dialysis clinic or holder of a special permit which is a group, corporation, or other association, the director may suspend the license or special permit of the organization or may suspend the license or special permit as to any individual person within the organization who is responsible for the violation.

SEC. 11. Section 1248.1 of the Health and Safety Code is amended to read:

1248.1. No association, corporation, firm, partnership, or person shall operate, manage, conduct, or maintain an outpatient setting in this state, unless the setting is one of the following:

(a) An ambulatory surgical center that is certified to participate in the Medicare program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act.

(b) Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1601 of Title 25 of the United States Code, and located on land recognized as tribal land by the federal government.

(c) Any clinic directly conducted, maintained, or operated by the United States or by any of its departments, officers, or agencies.

(d) Any primary care clinic licensed under subdivision (a) of Section 1204 *or any ambulatory surgical center licensed under subdivision (b) of Section 1204.*

(e) Any health facility licensed as a general acute care hospital under Chapter 2 (commencing with Section 1250).

(f) Any outpatient setting to the extent that it is used by a dentist or physician and surgeon in compliance with Article 2.7 (commencing with Section 1646) or Article 2.8 (commencing with Section 1647) of Chapter 4 of Division 2 of the Business and Professions Code.

(g) An outpatient setting accredited by an accreditation agency approved by the division pursuant to this chapter.

(h) A setting, including, but not limited to, a mobile van, in which equipment is used to treat patients admitted to a facility described in subdivision (a), (d), or (e), and in which the procedures performed are staffed by the medical staff of, or other healthcare practitioners with clinical privileges at, the facility and are subject to the peer review process of the facility but which setting is not a part of a facility described in subdivision (a), (d), or (e).

Nothing in this section shall relieve an association, corporation, firm, partnership, or person from complying with all other provisions of law that are otherwise applicable.

SEC. 12. Section 139.3 of the Labor Code is amended to read:

139.3. (a) Notwithstanding any other provision of law, to the extent those services are paid pursuant to Division 4 (commencing with Section 3200), it is unlawful for a physician to refer a person for clinical laboratory, diagnostic nuclear medicine, radiation oncology, physical therapy, physical rehabilitation, psychometric testing, home infusion therapy, outpatient surgery, or diagnostic imaging goods or services whether for treatment or medical-legal purposes if the physician or his or her immediate family, has a financial interest with the person or in the entity that receives the referral.

(b) For purposes of this section and Section 139.31, the following shall apply:

(1) "Diagnostic imaging" includes, but is not limited to, all X-ray, computed axial tomography magnetic resonance imaging, nuclear medicine, positron emission tomography, mammography, and ultrasound goods and services.

(2) "Immediate family" includes the spouse and children of the physician, the parents of the physician, and the spouses of the children of the physician.

(3) "Physician" means a physician as defined in Section 3209.3.

(4) A "financial interest" includes, but is not limited to, any type of ownership, interest, debt, loan, lease, compensation, remuneration, discount, rebate, refund, dividend, distribution, subsidy, or other form of direct or indirect payment, whether in money or otherwise, between a licensee and a person or entity to whom the physician refers a person for a good or service specified in subdivision (a). A financial interest also exists if there is an indirect relationship between a physician and the referral recipient, including, but not limited to, an arrangement whereby a physician has an ownership interest in any entity that leases property to the referral recipient. Any financial interest transferred by a physician to, or otherwise established in, any person or entity for the purpose of avoiding the prohibition of this section shall be deemed a financial interest of the physician.

(5) A "physician's office" is either of the following:

(A) An office of a physician in solo practice.

(B) An office in which the services or goods are personally provided by the physician or by employees in that office, or personally by independent contractors in that office, in

accordance with other provisions of law. Employees and independent contractors shall be licensed or certified when that licensure or certification is required by law.

(6) The "office of a group practice" is an office or offices in which two or more physicians are legally organized as a partnership, professional corporation, or not-for-profit corporation licensed according to subdivision (a) of Section 1204 of the Health and Safety Code for which all of the following are applicable:

(A) Each physician who is a member of the group provides substantially the full range of services that the physician routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel.

(B) Substantially all of the services of the physicians who are members of the group are provided through the group and are billed in the name of the group and amounts so received are treated as receipts of the group, and except that in the case of multispecialty clinics, as defined in subdivision (*l*) of Section 1206 of the Health and Safety Code, physician services are billed in the name of the multispecialty clinic and amounts so received are treated as receipts of the multispecialty clinic.

(C) The overhead expenses of, and the income from, the practice are distributed in accordance with methods previously determined by members of the group.

(7) Outpatient surgery includes both of the following:

(A) Any procedure performed on an outpatient basis in the operating rooms, ambulatory surgery rooms, endoscopy units, cardiac catheterization laboratories, or other sections of a freestanding ambulatory ~~surgery clinic~~ *surgical center*, whether or not licensed under paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code.

(B) The ambulatory surgery itself.

(c) (1) It is unlawful for a licensee to enter into an arrangement or scheme, such as a cross-referral arrangement, that the licensee knows, or should know, has a principal purpose of ensuring referrals by the licensee to a particular entity that, if the licensee directly made referrals to that entity, would be in violation of this section.

(2) It shall be unlawful for a physician to offer, deliver, receive, or accept any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for a referred evaluation or consultation.

(d) No claim for payment shall be presented by an entity to any individual, third-party payor, or other entity for any goods or services furnished pursuant to a referral prohibited under this section.

(e) A physician who refers to or seeks consultation from an organization in which the physician has a financial interest shall disclose this interest to the patient or if the patient is a minor, to the patient's parents or legal guardian in writing at the time of the referral.

(f) No insurer, self-insurer, or other payor shall pay a charge or lien for any goods or services resulting from a referral in violation of this section.

(g) A violation of subdivision (a) shall be a misdemeanor. The appropriate licensing board shall review the facts and circumstances of any conviction pursuant to subdivision (a) and take appropriate disciplinary action if the licensee has committed unprofessional conduct. Violations of this section may also be subject to civil penalties of up to five thousand dollars ($5,000) for each offense, which may be enforced by the Insurance Commissioner, Attorney General, or a district attorney. A violation of subdivision (c), (d), (e), or (f) is a public offense and is punishable upon conviction by a fine not exceeding fifteen thousand dollars ($15,000) for each violation and appropriate disciplinary action, including revocation of professional licensure, by the Medical Board of California or other appropriate governmental agency.

~~SEC. 12.~~

SEC. 13. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a

crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2373 **VERSION: AMENDED APRIL 5, 2006**

AUTHOR: PLESCIA **SPONSOR: MEDICAL TECHNOLOGIES INC.**

RECOMMENDED POSITION:

SUBJECT: AUTOMATED DRUG DELIVERY SYSTEM

Existing Law:

1) Permits the use of an automated drug delivery system (ADDS) in non-profit clinics licenced by the board under specified circumstances. (B&P 4186)

2) Permits skilled nursing and intermediate care facilities to use an ADDS to store and distribute drugs, and specifies requirements for the use of ADDSs in those facilities. (B&P 4119.1)

3) Defines "health facility" in general, and specifically defines "skilled nursing facility," "intermediate care facility," and "nursing facility." (H&S 1250(c), (d), (k))

4) Provides for skilled nursing and intermediate care facilities to use an ADDS to store and distribute drugs, and to track the movement of drugs into and out of the system. (H&S 1261.6)

5) Regulates the manner in which a pharmacist stocks and oversees the removal of drugs from an automated drug delivery system. (H&S 1261.6)

This Bill:

1) Expands the use of ADDS in nursing facilities. (H&S 1261.6(a)(2) Amended)

2) Deletes the requirement that medications removed from an ADDS be labeled specificly to a patient.

(H&S 1261.6(f)(6) Amended)

3) Permits the use of blister pack cards in an ADDS. (H&S 1261.6(i) Amended)

Comment:

1) Author's Intent. The author's intent is to broaden the use and type of automated drug delivery systems used in long-term care facilities. A letter written by the sponsor of the bill states that "the system description currently provided in H&S code 1261.6 does not specifically address a major type of standard industry packaging and a portion of the language in 1261.6(f)(6) is too limiting to enable the use of certain systems. As a result, few pharmacies/facilities are willing to undergo the expense required to install one of these systems. Specifically, the bill would include "blister pack" cards as an approved packaging technology

and clarify that facility or contract personnel licensed by law to administer drugs have access to the entire inventory of drugs stored in the system after the review and approval of a licensed pharmacist."

2) Suggested Amendment: If the board supports the measure then B&P section 4119.1, should be amended to allow nursing facilities use an ADDS to store and distribute drugs. This amendment would make the B&P code consistent with H&S 1261.6, as amended.

3) Previous Legislation. AB 809 (Chapter 310, Statutes of 2001), Automated Drug Delivery Systems, permitted the use of ADDs in clinics licensed by the board. AB 2184 (Chapter 342, Statutes of 2004), Automated Drug Delivery Systems, expanded the use of automated drug delivery system in skilled nursing facilities. AB 522 (Chapter 469, Statutes of 2005) revised existing law by 1) defining "pharmacy services" as the provision of both routine and emergency drugs and biologicals to meet the needs of the patient; 2) requiring a pharmacist reviewing an order for a drug to check for contraindications and adverse drug reactions when an automated drug delivery system is used; and 3) limiting access by licensed personnel to an automated drug delivery system to the prescribed drug authorized by the pharmacist and specific to the patient.

4) History.

2006

Apr. 6	Re-referred to Com. on HEALTH.
Apr. 5	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 14	Referred to Coms. on HEALTH and B. & P.
Feb. 24	From printer. May be heard in committee March 26.
Feb. 23	Read first time. To print.

AMENDED IN ASSEMBLY APRIL 5, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 2373

Introduced by Assembly Member Plescia

February 23, 2006

An act to amend Section 1261.6 of the Health and Safety Code, relating to health facilities.

LEGISLATIVE COUNSEL'S DIGEST

AB 2373, as amended, Plescia. Automated drug delivery system.

Existing law provides for skilled nursing and intermediate care facilities that use an automated drug delivery system to store and distribute drugs to accurately track the movement of drugs into and out of the system.

This bill would include nursing facilities within the scope of that requirement.

~~Existing law provides that individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.~~

~~This bill would further limit that access to those persons described above when operating within their professional scope of practice.~~

~~Existing law requires that review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law, and specifies that the review include specified inspections and reviews.~~

~~This bill would extend the scope of the review to include a related discussion with facility staff using the system.~~

Existing law requires that a pharmacist stock an automated drug delivery system, unless the system utilizes removable pockets,

drawers, or similar technology, in which case stocking may be done outside the facility and delivered to the facility under specified conditions.

This bill would specify that this exception applies to the use of removable pockets, cards, drawers, or similar technology.

Existing law exempts drugs dispensed from an automated drug delivery system that meets specified requirements from certain drug container labeling requirements if, among other things, those drugs are contained in unit dose packaging.

This bill would include within the definition of unit dose packaging drugs packaged in blister pack cards.

Existing law makes a violation of statutory requirements applicable to licensing of the above facilities a crime. By expanding the scope of the application of the above requirements to include nursing facilities that have an automated drug delivery system, this bill would change the definition of a crime, thereby imposing a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 1261.6 of the Health and Safety Code is amended to read:

1261.6. (a) (1) For purposes of this section and Section 1261.5, an "automated drug delivery system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or (k), of Section

1250 that has an automated drug delivery system provided by a pharmacy.

(3) For purposes of this section, "pharmacy services" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient as prescribed by a physician.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs ~~and operating within the scope of their professional scope of practice~~.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a

prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Section 4119.1 of the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(3) The pharmacy providing services to the facility pursuant to Section 4119.1 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(5) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(6) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system ~~shall be limited only to the drug as ordered by the prescriber and reviewed by the pharmacist and that is specific to the patient.~~ *shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist.* When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall ~~only~~ have access to the drug ordered for that scheduled time of administration.

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable ~~pockets or~~ *pockets, cards,* drawers, or similar technology, the stocking system may be done outside of

the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable ~~pockets~~ *pockets, cards,* or drawers is performed by a pharmacist or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable ~~pockets~~ *pockets, cards,* or drawers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the ~~pockets~~ *pockets, cards,* or drawers are properly placed into the automated drug delivery system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, *and* a review of all transaction records in order to verify the security and accountability of the ~~system, and a related discussion with facility staff using the~~ system.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration. *For purposes of this section, unit dose packaging includes blister pack cards.*

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a

crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2730 **VERSION: INTRODUCED**

AUTHOR: NATION **SPONSOR: AUTHOR**

RECOMMENDED POSITION:

SUBJECT: MEDI-CAL: CONTRACT DRUG LIST: ADVERTISING

Existing Law:

1) Permits the Department of Health Services (DHS) to enter into contracts with manufacturers of drugs, and requires DHS to maintain a list of those drugs for which contracts have been executed, known as the Medi-Cal contract drug list. Allows patients who are Medi-Cal eligible who lack prescription drug coverage, to purchase drugs at the Medi-Cal rate. (B&P 4425-4426)

2) Requires the Food and Drug Administration (FDA) to regulate the promotion of prescription drugs including the content of direct-to-consumer (DTC) advertising. (21 USC 502(n))

3) Requires advertisers to present accurate information and fairly represent both the benefits and risk of advertised drugs. (21 CFR 202.1(e))

4) Requires pharmaceutical companies to submit all drug advertisements to the FDA when they are first broadcast, published, or distributed through other means. (21 CFR 314.81(b)(3)(i))

This Bill:

1) Prohibits DHS from entering into a contract for a drug, or placing a drug on the Medi-Cal contract drug list, if the drug has been promoted through the use of direct-to-consumer advertising in California, unless either of the following conditions exists:

a. DHS is required to reimburse a provider for a drug that has been promoted through the use of direct-to-consumer advertising in California if the provider has obtained prior authorization from the department to prescribe the drug.
b. Regardless of whether prior authorization was obtained, DHS is required to reimburse a provider who submits an otherwise valid claim for the cost of a drug that was provided to a Medi-Cal beneficiary who began using the drug prior to January 1, 2007, as part of a prescribed therapy, unless that drug is no longer prescribed for the beneficiary's therapy.

2) Defines "direct-to-consumer advertising" as any promotional message or material regarding a drug that may be obtained only by prescription that satisfies each of the following:

a. Employs the brand or pharmacological name of the drug, or employs a description of the drug or its effects without identifying it by name.

b. Is distributed or made available to an audience that is not composed primarily of physicians and surgeons, or other medical professionals authorized to write prescriptions.
c. Takes place through in-person contact, or appears in any form of communications media, including the following:
    i. Print media, such as magazines, journals, and other periodicals, newspapers, and printed material distributed directly to consumers.
    ii. Broadcast media, such as radio and television.
    iii. Electronic media, such as the Internet.
    iv. Telephone communications systems, such as fax machines.

(Welfare and Institutions 14105.331 Added)

Comment:

1) Author's Intent. The author's intent is to "curtail wasteful spending on drug advertising. Pharmaceutical companies are advertising their products to the public without disclosing, among other details, all the side effects associated with the drug or the actual purpose of the drug. As a result, runaway advertising is driving up costs of products and health care."

2) DTC Snapshot. The following information is primarily from a 2002 Government Accounting Office Report, *Prescription Drugs, FDA Oversight of D-T-C Advertising Has Limitations.* (An excerpt of the report is attached.)

Advertising Budgets. In 2001, pharmaceutical companies spent a total of $49.4 billion on research and development (R&D) on new drugs and promotional advertising of existing drugs; $30.3 billion on R&D and $19.1 billion on total promotion. Of the $19.1 billion spent on promotion 80% ($15.3 billion) was targeted at physicians in the form of providing samples and sending sales representatives to meet with physicians; the remaining 20% ($2.7 billion) was spent on DTC advertising.

The GAO report states that between 1999 and 200, the number of prescription drugs dispensed fro the heavily advertised drugs rose 25%, but increased 4% for drugs that were not heavily advertised. Over the same period, prices rose 6% for the most heavily advertised drugs and 9% for the others.

Effectiveness of DTC Advertising. A 2003, report from the Harvard School of Public Health, *Demand Effects of Recent Changes in Prescription Drug Promotion*, May 29, 2003, found that advertising had an elasticity of .10, in five therapeutic classes that were studied, "which means that on average a 10% increase in DTC advertising of a drug within a class results in a 1% increase in sales in the class." While it's not surprising that advertising is effective, it is interesting that DTC advertising did not increase sales of individual drugs. "One possible explanation for this finding is that DTC advertising prompts previously untreated patients to talk to their doctors about advertised treatments, but the discussions may not lead to a prescription for a particular drug."

Types of Advertisements: The FDA permits three types of DTC advertisements, product claim ads, reminder ads, and help-seeking ads. Only the product claim ad is required to mention a drug by name, safety and effectiveness of the drug, a brief summary of benefit and risk, a major statement of risk, and provisions for finding out more information, such as a toll-free number.

Regulation and Enforcement: The FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) is responsible for overseeing and implementing regulations governing DTC advertisement. When the DDMAC finds an advertisement is in violation of the law, the DDMAC will send one of two enforcement letters to the pharmaceutical company; either an untitled or a warning letter. A company that receives a letter is asked to

submit a written response to the DDMAC describing the remedial action it has taken. The GAO found that "the FDA's oversight is generally effective in halting the dissemination of advertisements it views and identifies as misleading." In 2002, DDMAC's internal procedures for drafting regulatory letters were changed. The new procedures lengthen the time it takes DDMAC to draft and send letters to pharmaceutical companies. The increase time has resulted in letters arriving after advertising campaigns have run their course. As a result, consumers never see corrected advertisements.

5) History.

2006

Mar. 14 Referred to Com. on HEALTH.
Feb. 27 Read first time.
Feb. 25 From printer. May be heard in committee March 27.
Feb. 24 Introduced. To print.

ASSEMBLY BILL No. 2730

Introduced by Assembly Member Nation

February 24, 2006

An act to add Section 14105.331 to the Welfare and Institutions Code, relating to Medi-Cal.

LEGISLATIVE COUNSEL'S DIGEST

AB 2730, as introduced, Nation. Medi-Cal: contract drug list: advertising.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Services and under which qualified low-income persons receive health care benefits, including prescription drug benefits.

Existing law allows the department to enter into contracts with manufacturers of drugs, and requires the department to maintain a list of those drugs for which contracts have been executed, known as the Medi-Cal contract drug list.

This bill would make certain findings and declarations regarding direct-to-consumer advertising of prescription drugs. It would prohibit the department from entering into a contract for a drug, and from placing a drug on the Medi-Cal contract drug list, if the drug has been promoted in California through the use of direct-to-consumer advertising, as defined. The bill would, however, require the department to reimburse a provider for such a drug if the provider has obtained prior authorization from the department to prescribe the drug, or if the drug was provided to a Medi-Cal beneficiary who began using it before January 1, 2007, as part of a prescribed therapy, unless that drug is no longer prescribed for the beneficiary's therapy.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares the following:

(a) The United States is one of only a few countries that allow pharmaceutical companies to advertise prescription drugs.

(b) Direct-to-consumer prescription drug advertising is a category of promotional information about specific drug treatments provided directly to consumers by or on behalf of drug companies.

(c) Advertisements disseminated to the public are not required in order for pharmaceutical companies to sell their products.

(d) Since pharmaceutical companies have been allowed to broadcast advertisements that mention a prescription medication by name without disclosing all of the risks of that medication, consumer demand for medications has increased, resulting in a corresponding increase in the cost of prescriptions and health care delivery.

(e) While the pharmaceutical community has tried to convince the public, the United States Congress, and the federal Food and Drug Administration (FDA) that direct-to-consumer advertisements are educational rather than promotional, the goal of these ads is to ensure that patients obtain prescriptions from their doctors for a particular brand of medication, rather than for a competitor's product or for another form of therapy that may be more suitable for an individual patient.

(f) Physicians are under increasing pressure from patients who already suspect that health maintenance organization formularies restrict physicians from prescribing the best medication for each patient.

(g) The consequences of direct-to-consumer advertising of pharmaceutical drugs include the fact that a physician must spend time defending the reasons why the advertised drug is either unnecessary or detrimental to the patient's health, and the possibility that, if the physician declines to issue a prescription, the patient may turn to other sources, including the Internet, to obtain the product.

(h) According to the United States General Accounting Office, the investigational arm of Congress, pharmaceutical manufacturers spent 1.1 billion dollars in 1997, increasing to about 2.7 billion dollars in 2001, on direct-to-consumer prescription drug advertising alone, with expenditures increasing at double digit rates every year.

(i) Numerous studies have linked the increase in direct-to-consumer advertising to the exponential growth in prescription drug expenditures.

(j) In 1997, the FDA relaxed restrictions on the content of direct-to-consumer prescription drug advertising, withdrawing the prior requirement for a summary of side-effect and adverse reaction information and replacing it with a requirement for a statement about "major risks," but not "all risks," thereby making direct-to-consumer advertisements about prescription drugs more practicable.

SEC. 2. Section 14105.331 is added to the Welfare and Institutions Code, to read:

14105.331. (a) (1) Notwithstanding any other provision of this chapter, and except as provided in paragraphs (2) and (3), the department shall not enter into a contract for a drug, nor place a drug on the Medi-Cal contract drug list, if the drug has been promoted through the use of direct-to-consumer advertising in California.

(2) The department shall reimburse a provider for a drug that has been promoted through the use of direct-to-consumer advertising in California if the provider has obtained prior authorization from the department to prescribe the drug.

(3) Notwithstanding paragraph (2), regardless of whether prior authorization has been obtained, the department shall reimburse a provider who submits an otherwise valid claim for the cost of a drug that was provided to a Medi-Cal beneficiary who began using the drug prior to January 1, 2007, as part of a prescribed therapy, unless that drug is no longer prescribed for the beneficiary's therapy.

(b) For purposes of this section, "direct-to-consumer-advertising" means any promotional message or material regarding a drug that may be obtained only by prescription that satisfies each of the following:

(1) Employs the brand or pharmacological name of the drug, or employs a description of the drug or its effects without identifying it by name.

(2) Is distributed or made available to an audience that is not composed primarily of physicians and surgeons, or other medical professionals authorized to write prescriptions.

(3) Takes place through in-person contact, or appears in any form of communications media, including the following:

(A) Print media, such as magazines, journals, and other periodicals, newspapers, and printed material distributed directly to consumers.

(B) Broadcast media, such as radio and television.

(C) Electronic media, such as the Internet.

(D) Telephone communications systems, such as fax machines.

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United States General Accounting Office

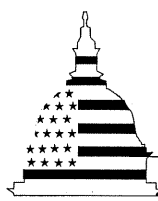
GAO

Report to Congressional Requesters

October 2002

PRESCRIPTION DRUGS

FDA Oversight of Direct-to-Consumer Advertising Has Limitations



G A O

Accountability * Integrity * Reliability

GAO-03-177

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Abbreviations

CDER	Center for Drug Evaluation and Research
DDMAC	Division of Drug Marketing, Advertising, and Communications
DTC	direct-to-consumer
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug and Cosmetic Act
HHS	Department of Health and Human Services
NIHCM	National Institute for Health Care Management Foundation
OCC	Office of the Chief Counsel
PhRMA	Pharmaceutical Research and Manufacturers of America

GAO
Accountability * Integrity * Reliability

United States General Accounting Office
Washington, DC 20548

October 28, 2002

The Honorable Susan Collins
The Honorable Barbara Mikulski
The Honorable James Jeffords
United States Senate

The Honorable Nick Rahall
The Honorable Joseph M. Hoeffel
House of Representatives

Prescription drug spending increased at an annual rate of about 18 percent from 1997 through 2001 and is the fastest growing component of health care spending in the United States. Among the many reasons cited for this increase are growth in the number of patients diagnosed with conditions that can be treated with pharmaceuticals and the development of innovative drugs for some conditions.[1] Spending on direct-to-consumer (DTC) advertising of prescription drugs has tripled in recent years. Pharmaceutical companies promote their products directly to consumers through advertisements in magazines, newspapers, and consumer brochures; on the Internet; and on radio and television. They also promote their products to physicians by sending sales representatives to their offices, providing free samples for distribution to patients, and advertising in professional journals.

The potential consequences of print and broadcast DTC advertising have prompted much debate. Supporters of DTC advertising maintain that it educates consumers about medical conditions and care options and that the increased use of prescription drugs that DTC advertising encourages has improved the public's health. Critics of DTC advertising contend that it is sometimes misleading, leads consumers to seek prescription drugs when other treatments may be more appropriate, and causes some patients to ask their physician to prescribe new drugs that are more expensive but may not be more effective than older drugs. Critics also argue that pharmaceutical companies spend too much money on drug promotion rather than on research and development initiatives.

[1]Robert W. Dubois, Anita J. Chawla, Cheryl A. Neslusan, Mark W. Smith, and Sally Wade, "Explaining Drug Spending Trends: Does Perception Match Reality?" *Health Affairs*, vol. 19 (2000), 231-39.

The Food and Drug Administration (FDA) regulates the promotion of prescription drugs, including the content of DTC advertisements, under the authority of the Federal Food, Drug and Cosmetic Act (FFDCA).[2] The act sets general standards for FDA's regulation of prescription drug advertising directed to consumers and physicians. Regulations implementing the act require that advertisements present accurate information and fairly represent both the benefits and the risks of the advertised drug.[3] The Division of Drug Marketing, Advertising, and Communications (DDMAC) within FDA's Center for Drug Evaluation and Research (CDER) is responsible for implementing the regulations governing DTC advertising. Under the regulations, pharmaceutical companies are required to submit all drug advertisements to FDA when they are first disseminated to the public (that is, broadcast, published, or otherwise distributed).[4] In 1997, FDA issued draft guidance to clarify and offer options on how these regulations applied to advertisements broadcast directly to consumers on radio and television.[5] Since that time, the number of broadcast advertisements for prescription drugs has increased greatly. At the same time, the number of regulatory letters sent by FDA to pharmaceutical companies requesting that the companies remove misleading advertisements from circulation has decreased, leading some observers to question FDA's ability to enforce its regulations. Others argue that this decrease has occurred because pharmaceutical companies are doing a better job of meeting FDA's requirements.

In light of these developments, you asked us to (1) compare spending by pharmaceutical companies on DTC advertising with spending on all promotional activities and on research and development, (2) evaluate the effect of DTC advertising on prescription drug spending and utilization, and (3) evaluate the extent and effectiveness of FDA's oversight of DTC advertising since FDA issued its 1997 draft guidance for broadcast advertisements.

To assess the trends in spending on DTC advertising, overall promotion, and research and development, we reviewed recent reports from the pharmaceutical industry and other organizations. To analyze the effect of

[2]21 U.S.C. § 502(n).

[3]21 C.F.R. § 202.1(e).

[4]21 C.F.R. § 314.81(b)(3)(i).

[5]The guidance was finalized in 1999.

DTC advertising on drug spending and utilization, we reviewed studies on pharmaceutical sales, examined surveys of consumer responses to DTC advertising, and reviewed studies on the impact of DTC advertising.[6] To evaluate the extent and effectiveness of FDA's oversight of DTC advertising, we reviewed federal regulations, and regulatory letters, and interviewed officials from several offices within FDA, including DDMAC. We also interviewed pharmaceutical industry representatives and other key stakeholders, including public interest groups and representatives of the advertising industry. We conducted our work from February 2002 through September 2002 in accordance with generally accepted government auditing standards. See appendix I for a detailed discussion of our scope and methodology.

Results in Brief

Pharmaceutical companies spend more on research and development initiatives than on all drug promotional activities, including DTC advertising. According to industry estimates, pharmaceutical companies spent $30.3 billion on research and development and $19.1 billion on all promotional activities, which includes $2.7 billion on DTC advertising, in 2001. Pharmaceutical companies have increased spending on DTC advertising more rapidly than they have increased spending on research and development. Between 1997 and 2001, DTC advertising spending increased 145 percent, while research and development spending increased 59 percent. Promotion to physicians accounted for more than 80 percent of all promotional spending by pharmaceutical companies in 2001. Total promotional spending was equivalent to 12 percent of drug sales in the United States in 2001.

DTC advertising appears to increase prescription drug spending and utilization. Drugs that are promoted directly to consumers often are among the best-selling drugs, and sales for DTC-advertised drugs have increased faster than sales for drugs that are not heavily advertised to consumers. Most of the spending increase for heavily advertised drugs is the result of increased utilization, not price increases. For example, between 1999 and 2000, the number of prescriptions dispensed for the most heavily advertised drugs rose 25 percent, but increased only 4 percent for drugs that were not heavily advertised. Over the same period,

[6]In this report, we use three terms to describe the magnitude of prescription drug use. "Utilization" refers to the number of prescriptions dispensed. "Spending" and "sales" refer to the amount of money spent for prescription drugs and are a function of both utilization and price.

prices rose 6 percent for the most heavily advertised drugs and 9 percent for the others. The concentration of DTC spending on a small number of drugs for chronic diseases that are likely to have high sales anyway and the simultaneous promotion of these drugs to physicians may contribute to increased utilization and thereby increase sales of DTC-advertised drugs. The recent research literature shows that DTC advertising may cause increases in drug utilization and sales in some cases. In addition, consumer surveys have consistently found that about 5 percent of consumers (or, by our estimate, about 8.5 million consumers annually) have both requested and received from their physician a prescription for a particular drug in response to seeing a DTC advertisement.

While generally effective at halting the dissemination of advertisements it reviews and identifies as misleading, FDA's oversight of DTC advertising has limitations. DDMAC focuses on advertisements that will be widely circulated or that are the most likely to impart misleading impressions of a drug to consumers. For example, DDMAC reviews all broadcast DTC advertisements because of the large number of people who will see them. FDA issues regulatory letters for a small percentage of the advertisements it reviews. From August 1997 through August 2002, FDA issued 88 regulatory letters for violative DTC advertisements. FDA officials told us that pharmaceutical companies that have received regulatory letters have invariably ceased dissemination of the misleading advertisement. However, FDA's oversight has not prevented some pharmaceutical companies from repeatedly disseminating new misleading advertisements for the same drug, and some pharmaceutical companies have failed to submit in a timely manner all newly disseminated advertisements to FDA for review. Furthermore, FDA's oversight has been adversely affected by a January 2002 change in its procedures for reviewing draft regulatory letters that was directed by the Department of Health and Human Services (HHS). This change has significantly increased the time between DDMAC's identification of a misleading advertisement and FDA's request to remove it from dissemination, with the result that some regulatory letters may not be issued until after the advertising campaign has run its course.

In light of the delay caused by the change in policy for review of draft DTC regulatory letters, we are recommending that HHS expedite the review of these letters to ensure that misleading DTC advertisements are withdrawn as soon as possible once identified. In its comments on a draft of this report, HHS explained that the purpose of the change in procedure was to ensure that the letters are based on a solid legal foundation and promote voluntary compliance. HHS agreed that it is important to issue DTC

regulatory letters quickly and said that it intends to reduce the number of days that the letters are under review.

Background

Prescription drug spending and utilization have increased rapidly in recent years. Part of the increase is due to growth in the number of patients diagnosed with conditions that can be treated with pharmaceuticals and the development of innovative drugs for some conditions. The promotion of prescription drugs is regulated by FDA. FDA's regulations and subsequently issued guidance contain specific requirements and explanations regarding the content of advertisements that promote prescription drugs. When requirements are not met, FDA may issue a regulatory letter requesting that the advertisement be withdrawn or revised.

Reasons for Increased Prescription Drug Spending and Utilization

Prescription drug spending has risen steadily over the past decade. Spending on prescription drugs now represents 10 percent of health care expenditures in the United States, and adults aged 65 and older spend nearly 3 percent of their total household expenditures on medications.[7] Increases in overall drug spending are the result of three types of changes in drug prices and drug use: increases in utilization, that is, the number of prescriptions dispensed; price increases; and a shift from older drugs to new, more expensive drugs (newly marketed drugs are generally more expensive than older drugs in the same class). The National Institute for Health Care Management Foundation (NIHCM) reported that overall spending on prescription drugs in the United States increased 17.1 percent from 2000 to 2001: an increase in the number of prescriptions accounted for a 6.7 percent increase, price increases for a 6.3 percent increase, and shifts to higher-cost drugs for a 4.1 percent increase.[8]

Prescription drug utilization in the United States has shown a steady increase over the past decade. The number of prescriptions dispensed in retail pharmacies has grown at an average annual rate of 6 percent since

[7]David H. Kreling, David A. Mott, Joseph B. Wiederholt, Janet Lundy, and Larry Levitt, *Prescription Drug Trends: A Chartbook Update*, pub. no. 3112 (Washington, D.C.: The Henry J. Kaiser Family Foundation, 2001).

[8]NIHCM Foundation, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs* (Washington, D.C.: NIHCM Foundation, 2002).

1992, reaching nearly 3 billion in 2000.[9] Among the factors besides DTC advertising and promotion to physicians that may contribute to this increased utilization are an aging population that is more dependent on multiple medications for treatment; new medications for conditions that had less effective previous treatments, such as high cholesterol; and increased insurance coverage for medications. In addition, the number of patients diagnosed with chronic conditions for which pharmaceutical treatments are available has increased dramatically. For example, the number of people with arthritis, one of the most frequent causes of disability in the United States, increased from an estimated 38 million in 1990 to 43 million in 1997.[10] Furthermore, for some conditions, such as high cholesterol, increased drug utilization has resulted from biomedical research that has led to a broadening of the guidelines for treatment with drugs.[11]

Countries that do not allow DTC advertising and have publicly funded health systems have also experienced increased drug utilization, and therefore increased spending, because of these same factors. According to a drug marketing research firm, retail pharmacy sales from April 2001 through April 2002 rose 16 percent in the United States, 16 percent in Canada, 10 percent in Germany, and 12 percent in the United Kingdom.[12]

FDA's Requirements for the Content of DTC Advertisements

FDA regulations describe several types of prescription drug advertisements, including DTC advertisements, and the extent to which they are subject to regulation. One type, product claim advertisements, usually mentions a drug's name and the condition it is intended to treat and describes the risks and benefits associated with taking the medication.

[9]Kreling, Mott, Wiederholt, Lundy, and Levitt, *Prescription Drug Trends: A Chartbook Update*, 8.

[10]Centers for Disease Control and Prevention, "Prevalence of Arthritis—United States, 1997," *MMWR*, vol. 50 (2001), 334-6.

[11]National Institutes of Health, *Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), Executive Summary*, NIH pub. no. 01-3670 (Rockville, Md.: NIH, May 2001.)

[12]IMS Health, Inc.,"IMS Health Reports 11% Growth in Retail Pharmacy Drug Sales for the 12 Months to April 2002" (Fairfield, Ct.: IMS Health, 2002), http://www.imshealth.com/public/structu (downloaded September 26, 2002). Based on sales from wholesalers to retail pharmacies, with sales measured in U.S. dollars at a constant exchange rate.

The regulations specify, among other things, that product claim advertisements (1) cannot be false or misleading; (2) must present a fair balance between the risks and the benefits of a drug product; (3) must reveal facts that are material to the representations made in the advertisement or the consequences of using the product as advertised; and (4) must, depending on the medium, either disclose all the risks listed in the product's labeling or make "adequate provision" to disseminate the approved product labeling through other means to the advertisement's audience. Table 1 shows some of the requirements for print and broadcast product claim advertisements.

Table 1: Selected Requirements for Contents of Print and Broadcast Product Claim Advertisements

Advertising medium	Regulatory requirements	Explanation
Print and broadcast	Cannot be false or misleading	Must present information that is not inconsistent with product label
	Must present fair balance	Must include risks and benefits of a drug product
	Must present "facts material"	Must present information relevant to representations made, and describe consequences that may result from recommended use
Print only	Must describe risks	Must disclose all risks in a product's labeling
Broadcast only	Must describe risks	Must present major side effects and contraindications[a] in audio or audio and visual form
	Must make "adequate provision" for directing consumers to labeling information, or provide a brief summary of all necessary information related to risks	Must provide additional sources where consumers can find complete information, such as a toll-free telephone number, a Web site, and a print advertisement in a magazine, and by contacting their physicians; otherwise must summarize risks

[a]Contraindications are symptoms or conditions that make a drug treatment inadvisable.

Sources: 21 C.F.R. § 202; FDA, *Guidance for Industry: Consumer-directed Broadcast Advertisements* (Washington, D.C.: FDA, Aug. 1997).

In 1997, FDA issued draft guidance on how broadcast product claim DTC advertisements could communicate information about the risks of using a drug by finding mechanisms by which to get the product labeling

information to consumers, and thereby meet the adequate provision portion of its regulations.[13] Before this provision of the regulation was clarified in 1997, pharmaceutical companies generally had to provide all of the risk information associated with the medication during the broadcast advertisement. Including all of this risk information in a broadcast DTC advertisement increased the length of the advertisement to the point that such advertising was largely impractical. After the guidance was issued, pharmaceutical companies had an alternative to the requirement that all risks in broadcast advertisements be disclosed. Pharmaceutical companies could meet the regulatory requirements by presenting the major side effects, either in audio or in audio and visual form, and by telling consumers where to find additional information, including how or where to obtain the approved product labeling.

A second type of advertisement is reminder advertisements. These may disclose the name of the product and dosage form (e.g., tablet, syrup) or cost information, but they are not permitted to present its intended use or to make any claims or representations about the product. Under FDA regulations, reminder advertisements are exempt from the risk disclosure requirements.

A third type of advertisement is help-seeking advertisements, which are not regulated by FDA. They do not identify drugs by name and generally discuss a disease or condition and advise the print or broadcast audience to "see your doctor" for possible treatments.

FDA Regulatory Letters

In an effort to stop dissemination of misleading DTC advertisements, FDA sends regulatory letters to companies that are in violation of its regulations. These letters are of two types—untitled letters and warning letters. Untitled letters address violations such as overstating the effectiveness of the drug, suggesting a broader range of indicated uses than the drug has been approved for, and making misleading claims because of inadequate context or lack of balanced risk information. Warning letters address more serious violations, including safety or health risks, or continued violations of the act. Warning letters advise a pharmaceutical firm that FDA may take further enforcement actions, such as seeking judicial remediation, without notifying the company, and

[13]FDA, *Guidance for Industry: Consumer-directed Broadcast Advertisements* (Washington, D.C.: FDA, Aug. 1997).

generally ask the firm to conduct a new advertising campaign to correct inaccurate impressions left by the advertisement. A company that receives either type of letter from FDA is asked to submit a written response to the agency within 14 days describing the remedial actions it has taken.

Pharmaceutical Companies Spend More on Research and Development than on DTC Advertising

Pharmaceutical companies spend more on research and development than on DTC advertising or on all promotional activities combined, according to industry sources. Nonetheless, spending for DTC advertising has increased much faster than spending for all promotional activities or for research and development. More than 80 percent of all promotional spending is directed toward physicians rather than consumers.

Despite Rapid Growth in Spending on DTC Advertising, Pharmaceutical Companies Spend More on Research and Development

According to industry analyses, spending on research and development was more than 10 times higher than spending on DTC advertising in 2001.[14] Pharmaceutical companies spent an estimated $30.3 billion on research and development and $19.1 billion on all promotional activities, including $2.7 billion on DTC advertising in 2001. However, the growth rate of spending on DTC advertising is higher than the rate of increase for spending on total promotion or spending on research and development. As table 2 shows, from 1997 through 2001, spending on DTC advertising increased from $1.1 billion to an estimated $2.7 billion, spending on total promotion increased from $11.0 billion to an estimated $19.1 billion, and research and development spending increased from $19.0 billion to an estimated $30.3 billion.

[14]Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2002* (Washington, D.C.: Pharmaceutical Research and Manufacturers of America, 2002); IMS Health Integrated Promotional Services, "Total U.S. Promotional Spending by Type, 2001" (Fairfield, Ct.: IMS Health, 2002), http://www.imshealth.com/public/structu (downloaded July 17, 2002). We did not independently verify the amounts reported by the Pharmaceutical Research and Manufacturers of America and IMS Health. However, many researchers have consistently cited these data sources, and they represent the best available information.

Table 2: DTC Advertising Spending Compared to Spending on Total Promotion and Research and Development from 1997 to 2001

Dollars in billions

	1997	1998	1999	2000	2001	Percentage spending increase, 1997-2001
DTC	$1.1	$1.3	$1.8	$2.5	$2.7	145
Total promotion[a]	11.0	12.5	13.9	15.7	19.1	74
Research and development	19.0	21.1	22.7	26.0	30.3[b]	59

[a]Total promotion includes DTC advertising.

[b]Estimated spending on research and development.

Sources: For 1997 to 2000 data, Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2002*, 18, 75; for 2001 promotional spending estimates, IMS Health, "Total U.S. Promotional Spending by Type, 2001."

In recent years there has been a shift of DTC advertising from print media to television broadcasts.[15] The percentage of DTC spending devoted to print advertisements declined from 74 percent in 1997 to 35 percent in 2001. Conversely, spending on television advertising increased from 25 percent of all DTC spending in 1997 to 64 percent in 2001. Prescription drug promotion on television escalated from 25 percent to 53 percent of the total spending on DTC advertising from 1997 to 1998.

Most Promotional Spending Is Directed to Physicians

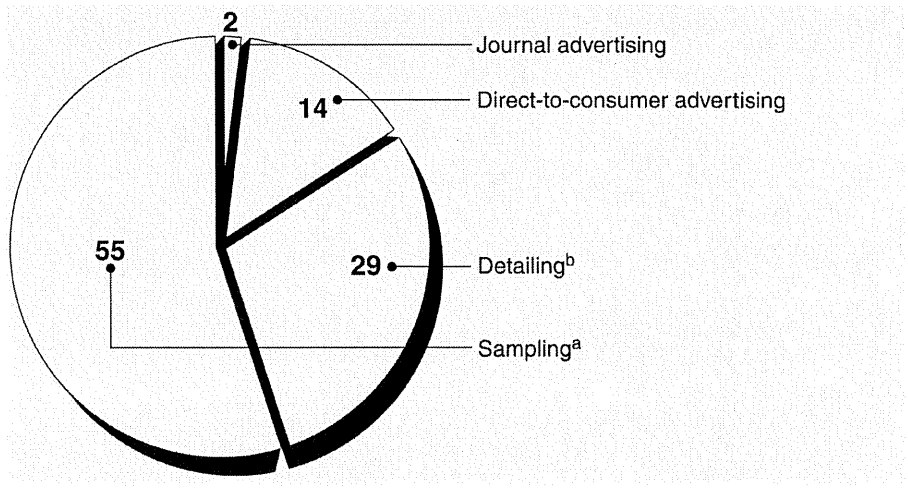
Most promotional spending is targeted to physicians. In each year from 1997 to 2001, providing samples to office-based and hospital-based physicians and sending sales representatives to meet with physicians (practices known as sampling and detailing, respectively) accounted for more than 80 percent of expenditures on promotional activities.[16] (See fig. 1.) The ratio of total promotional spending to drug sales remained fairly

[15]Television broadcasts constitute the majority of nonprint DTC advertising spending.

[16]Kreling, Mott, Wiederholt, Lundy, and Levitt, *Prescription Drug Trends: A Chartbook Update*; IMS Health Integrated Promotional Services, "Total U.S. Promotional Spending by Type, 2001." These figures do not include educational meetings arranged by pharmaceutical companies for physicians, which are not generally considered to be promotional activities. Pharmaceutical companies spent about $1.9 billion on educational meetings in 2000. (See NIHCM Foundation, *Prescription Drugs and Mass Media Advertising, 2000* (Washington, D.C.: NIHCM Foundation, 2001)).

constant from 1997 to 2001. In 2001, promotional spending was equivalent to 12 percent of drug sales in the United States.

Figure 1: Spending on Pharmaceutical Promotional Activities, 2001



[a]The practice of providing samples during sales visits to office-based physicians.

[b]Sales activity of pharmaceutical sales representatives directed to office-based and hospital-based physicians.

Source: IMS Health, "Total U.S. Promotional Spending by Type, 2001."

DTC Advertising Appears to Increase Prescription Drug Spending and Utilization

Drugs that are promoted directly to consumers often are among the best-selling drugs, and sales for DTC-advertised drugs have increased faster than sales for drugs that are not heavily advertised to consumers. Most of the spending increase for heavily advertised drugs is the result of increased utilization, not price increases. DTC advertising is concentrated among a small number of drugs for chronic conditions and many of these same drugs are also promoted to physicians, both factors that may lead to increased sales. To date, the few studies that have examined the effects of DTC spending on prescription drug spending and utilization have found that DTC advertising increases both. In addition, there is clear evidence from consumer surveys that DTC advertising encourages consumers to request prescriptions for specific brand-name drugs from their physicians and that some physicians provide the requested prescription.

Many DTC-Advertised Drugs Are Best Sellers

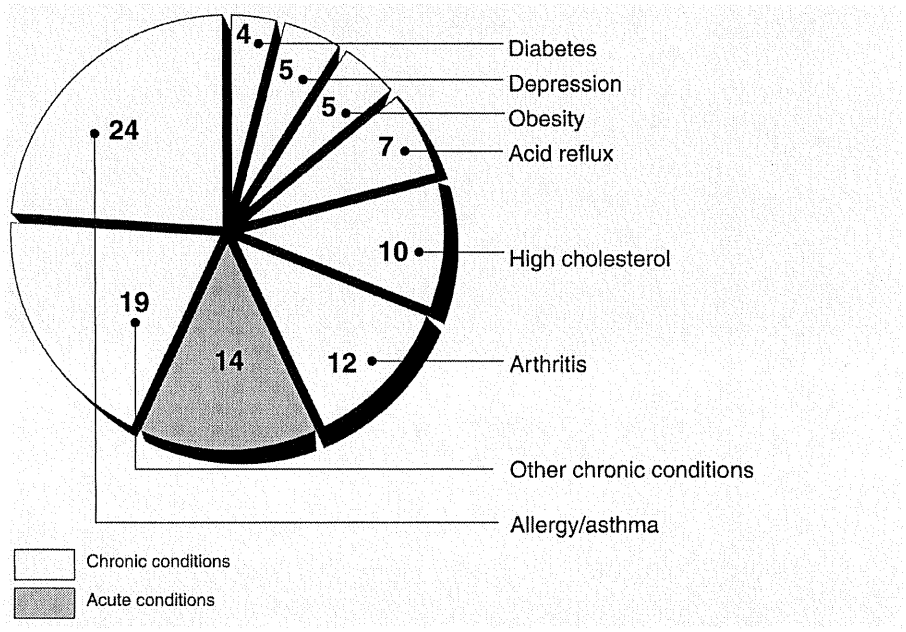
Drugs with high DTC spending are among the best-selling drugs. For example, in 2000, 22 of the 50 drugs with the highest DTC spending were among the top 50 in sales.[17] Furthermore, sales of drugs with the highest DTC spending have risen more quickly than sales of other drugs. For example, NIHCM reported that expenditures for the 50 most heavily advertised drugs increased 32 percent between 1999 and 2000, while expenditures for all other drugs increased 14 percent. Most of this expenditure increase results from increased utilization (that is, an increase in prescriptions filled), not from price increases. Among the 50 most heavily advertised drugs, the number of prescriptions dispensed rose 25 percent between 1999 and 2000, compared to a 4 percent increase for other drugs. During the same period, prices increased 6 percent for the heavily advertised drugs, and 9 percent for other drugs.

DTC-Advertised Drugs Are for Chronic Conditions and Are Often Promoted to Physicians

Concentration of DTC spending on a small number of drugs for chronic conditions that are likely to have high sales and the promotion of these same drugs to physicians may also contribute to increased utilization. Almost all spending on DTC advertising is concentrated among a small number of drugs that treat chronic conditions and therefore must be taken repeatedly. (See fig. 2.) These drugs are relatively new and are still under patent protection. According to NIHCM, the 50 drugs with the highest DTC advertising spending in 2000 accounted for 95 percent of all DTC advertising spending that year, and the top 15 DTC-advertised drugs accounted for 54 percent of all DTC advertising spending. All of the top 15 DTC-advertised drugs were for chronic conditions: 6 for allergy or asthma, 3 for high cholesterol, 2 for arthritis, and 1 each for acid reflux, depression, obesity, and impotence. (See table 3.) Only one of the 50 most heavily advertised drugs was an antibiotic, a drug class that is used episodically. In some drug categories, a small number of pharmaceuticals that are heavily advertised account for the vast majority of sales. For example, in 2000 three oral antihistamines, Claritin, Allegra, and Zyrtec, accounted for 86 percent of all oral antihistamine sales, and all three of them were among the 15 most heavily advertised drugs.

[17]NIHCM Foundation, *Prescription Drugs and Mass Media Advertising, 2000.*

Figure 2: Percentage of Sales for Chronic and Acute Conditions Treated by the 50 Drugs with the Highest Spending on DTC Advertising, 2000



Source: GAO analysis of data from NIHCM Foundation, *Prescription Drugs and Mass Media Advertising, 2000.*

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2856 **VERSION: INTRODUCED**

AUTHOR: HANCOCK **SPONSOR: AUTHOR**

RECOMMENDED POSITION:

SUBJECT: INFORMED CONSENT: PRESCRIPTION MEDICATION OFF-LABEL USE

Existing Law:

Food and Drug Administration's (FDA) general position is to allow off-label prescribing if the off-label use is generally accepted practice and there is some scientific evidence that the use is effective.

This Bill:

1) Requires a physician and surgeon to obtain informed consent from a patient before prescribing, administering, or furnishing a prescription medication for an off-label use.
(B&P 2295 Added)

2) Requires a physician and surgeon to inform the patient verbally, in easily understood terms, of all of the following information:

i. The medication is furnished to treat a condition that is not within the indications approved for that medication by the Food and Drug Administration.
ii. The nature, degree, duration, and probability of the side effects and the significant risks of the medication that are commonly known by the medical profession, including the medication's adjuvants, and the degree to which the side effects of the medication may be controlled.
iii. A division of opinion exists as to the efficacy of the use of the medication.
iv. A description of the effect of the medication on the human body.
v. The dosage deemed medically necessary to treat the patient's condition.
vi. The median age group for which the medication is prescribed.
vii. Available and appropriate medical alternatives to the medication and the reasons the physician and surgeon recommendations the medication instead.
viii. Available and appropriate medical alternatives to the medication and the reasons the physician and surgeon recommends the medication instead

3) Requires a physician or surgeon to advise the patient that he or she is free to withhold or withdraw consent at any time to the prescribing, administering, or furnishing of the medication.
(B&P 2295 Added)

4) Defines "off-label use" to mean prescribing, administering, or furnishing a prescription medication to treat a condition that is not within the indications for that medication approved by the federal Food and Drug Administration. (B&P 2295 Added)

Comment:

1) Author's Intent. The author's intent is to "promote patient awareness by providing patients full and complete information about medications being prescribed for an off-label use so they can make an informed health care decision. Off-label treatments have medical risks, and patients should be informed of the medical risks especially since some off-label treatments have been linked to deaths or severe side effects. Armed with the knowledge that a prescription is off-label, patients might ask more questions; seek other sources of information, such as the Web; watch more closely for side effects; or ask for an approved treatment instead."

2) Off Label Use. Off-label use, the practice of prescribing a drug for conditions other than those approved by the FDA, is a widely accepted and generally safe practice. The use of off-label prescribing for infants, children, and adolescents is common practice because so few drugs (about twenty percent of all drugs) approved by the FDA are approved for use by children. The American Medical Association (AMA) estimates that about forty percent of the all prescriptions are for off-label uses.

3) History.

2006

Mar. 20 Referred to Coms. on HEALTH and JUD.
Feb. 27 Read first time.
Feb. 25 From printer. May be heard in committee March 27.
Feb. 24 Introduced. To print.

ASSEMBLY BILL No. 2856

Introduced by Assembly Member Hancock

February 24, 2006

An act to add Section 2295 to the Business and Professions Code, relating to medical care.

LEGISLATIVE COUNSEL'S DIGEST

AB 2856, as introduced, Hancock. Informed consent: prescription medication off-label use.

Existing law, the Medical Practice Act, creates the Medical Board of California that, through its divisions, is responsible for the licensure and regulation of physicians and surgeons. The act imposes certain requirements on physicians and surgeons, including requiring that they provide specified information to patients for particular treatments, and the act makes a violation of those requirements a crime.

This bill would require a physician and surgeon to obtain informed consent from a patient before prescribing, administering, or furnishing a prescription medication for an off-label use, as defined. The bill would specify information that a physician and surgeon is required to provide in order to obtain the patient's informed consent.

Because the bill would specify an additional regulatory requirement under the Medical Practice Act, the violation of which is a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. (a) The Legislature finds and declares the following:

(1) The right of every patient to receive the basic information that is required to provide full and informed consent is a fundamental tenet of good public health policy and an established principle of law.

(2) Existing law requires health care providers to explain to patients medical procedures and treatments before administering those procedures and treatments.

(b) It is the intent of the Legislature that every patient be provided full and complete information about medical procedures so that the patient is able to make an informed health care decision. In particular, it is the intent of the Legislature to specify procedures for obtaining informed consent from a patient before prescribing, administering, or furnishing a prescription medication for a use that has not been approved by the federal Food and Drug Administration.

SEC. 2. Section 2295 is added to the Business and Professions Code, to read:

2295. (a) Before prescribing, administering, or furnishing a prescription medication for an off-label use, a physician and surgeon shall obtain informed consent from the patient. For these purposes, the physician and surgeon shall inform the patient verbally, in easily understood terms, of all of the following information:

(1) The medication is furnished to treat a condition that is not within the indications approved for that medication by the federal Food and Drug Administration.

(2) The nature, degree, duration, and probability of the side effects and the significant risks of the medication that are commonly known by the medical profession, including the medication's adjuvants, and the degree to which the side effects of the medication may be controlled.

(3) A division of opinion exists as to the efficacy of the use of the medication.

(4) A description of the effect of the medication on the human body.

(5) The dosage deemed medically necessary to treat the patient's condition.

(6) The median age group for which the medication is prescribed.

(7) Available and appropriate medical alternatives to the medication and the reasons the physician and surgeon recommends the medication instead.

(b) After providing the information described in subdivision (a), the physician and surgeon shall advise the patient that he or she is free to withhold or withdraw consent at any time to the prescribing, administering, or furnishing of the medication.

(c) "Off-label use" for purposes of this section, means prescribing, administering, or furnishing a prescription medication to treat a condition that is not within the indications for that medication approved by the federal Food and Drug Administration.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2877 **VERSION: AMENDED APRIL 6, 2006**

AUTHOR: FROMMER **SPONSOR: AUTHOR**

RECOMMENDED POSITION:

SUBJECT: PRESCRIPTION DRUGS: IMPORTATION: PROCUREMENT.

Existing Law:

1) Requires non-resident pharmacies to be licensed by the board. (B&P 4112)

2) Prohibits the importation of prescription drugs except by a drug manufacturer. (21CFR 381)

3) Authorizes the Department of General Services (DGS) to enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs, and authorizes the department to obtain from them discounts, rebates, or refunds as permissible under federal law. (Govt Code 14977-14981)

4) Requires four state agencies to participate in the program and authorizes other state, local, and public agency governmental entities to elect to participate in the program. (Govt Code 14977-14981)

This Bill:

1) Makes a number of legislative findings about the costs and necessity of prescription drugs.

2) Establishes the California Rx Prescription Drug Web Site Program. (H&S 110242 Added)

3) Requires the Department of Health Services (DHS) to establish a Web Site on or before July 1, 2007 that will provide consumers with information on how to purchase prescription drugs more affordably. The Web Site would include the following information:

a. The availability of a prescription drug benefit through Medicare, including the Voluntary Prescription Drug Benefit.
b. Discount drug programs available through the state.
c. Discount drug programs operated by drug manufacturers.
d. Canadian pharmacies that are approved by the department.
e. International pharmacies (Canada, England, and Ireland) that provide mail order service to the Untied States and contract with the department.
f. Links to any other Web sites deemed appropriate by the department.

(H&S 110242 Added)

4) Requires the Web Site to include price comparisons between typical pharmacy prices and international pharmacy prices for the 50 most commonly prescribed drugs. (H&S 110242 Added)

5) Establishes the requirements that must be met for DHS to "certify" a pharmacy located in Canada, England, or Ireland to include:

a. Verification of licensure by the appropriate province or country.
b. Compliance with the requirements that must be met by non-resident pharmacies. This determination will be made in consultation with the board.
c. Requires a prescription from the patient's personal physician.
d. Requires a patient medical history.
e. Requires a signed patient agreement.
f. Requires prescriptions to be mailed in original packaging.
g. Requires physical address and phone number for the pharmacy on the pharmacy Web site.
h. Prohibits the pharmacy from furnishing the following drugs:
    i. Controlled substances.
    ii. Biologics.
    iii. Infused drugs.
    iv. Intravenous drugs.
    v. Drugs inhaled during surgery.
    vi. Drugs requiring refrigeration or that are otherwise inappropriate for mail delivery.
i. Sale of only drugs approved by the country in which the pharmacy is located.
j. Comply with California law relating to drug pedigree.
k. Prohibits requiring patients to sign a waiver of liability.
l. Requires the pharmacy to maintain a customer service department.
m. Requires the pharmacy to employ professionals that are licensed in good standing.
n. Requires the pharmacy to comply with California privacy laws.
o. Prohibits filling a prescription if the patient hasn't taken the drug previously.
p. Prohibits furnishing drugs that have no equivalent approved by the FDA.

(H&S 110242 Added)

6) Permits the department to remove approved pharmacies from the Web site if the pharmacy fails to meet any of the above listed requirements. (H&S 110242 Added)

7) Permits the department to assess a fee on international pharmacies to fund this act.
(H&S 110242 Added)

8) Requires the DHS to establish the California Rx Prescription Drug Hotline (hotline) to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices. (H&S 1010243 Added)

9) Requires DHS to establish a low-cost 1-900 telephone number on or before July 1, 2006 and to limit the cost per call to the hotline to no more than 50 cents per call. The hotline would provide the same information as the California Rx Prescription Drug Web Site.
(H&S 1010243 Added)

10) Requires DGS to develop strategies for the state to achieve savings through greater use of generic drugs and would revise the report requirements.
(Govt Code 14982 Amended)

11) Repeals an outdate provision requiring DGS to submit a report to the Legislature relating to the department's drug purchasing program. (Govt Code 14981 Repealed)

Comment:

1) Author's Intent. The author's intent is to provide relief for Californians who are "fed up with sky-high pharmaceutical drug prices and concerned about the safety of those drugs." This bill is a conglomeration of AB 74, AB 76, and AB 306.

2) Importation. Existing federal law generally restricts the importation of prescription drugs to drug manufacturers. Federal law can permit the importation of prescription drugs by drug wholesalers and pharmacies if the Secretary of Health and Human Services (Secretary) issues a finding that such a practice would be safe. Such a finding has not been issued by the Secretary.

The Food and Drug Administration (FDA) has for many years allowed individuals to purchase drugs abroad in limited amounts and bring them into the United States for personal use. Recent statements by FDA officials have reinforced that the FDA does not intend to prosecute individuals who import drugs for their own use. However, the FDA has taken legal action against some storefronts that assist consumers in ordering drugs from Canadian pharmacies at lower prices. The FDA has also taken legal action against entities that serve as middlemen between Canadian drug suppliers and those state and local governments that have sought to purchase Canadian drugs for their beneficiaries. In recent months the FDA has also stpeed up confiscation of drugs mailed to the US from non US pharmacies.

3) Price Controls. Consumers seek to purchase drugs from Canadian and EC pharmacies to save money. Drug prices are lower in Canada because the Canadian government has a system to control drug prices. ***Branded*** drugs can commonly be purchased from Canadian pharmacies at substantial discounts. However, US prices are generally lower for ***generic*** drugs.

4) Affordability. The board has been sympathetic to the difficulty of those without drug insurance have to obtain the drugs they need.

Much of the public debate regarding the importation of drugs from Canada has focused on the legality of importing drugs. Consumers are seeking Canadian and European Community drugs because of lower prices not because of problems with drug availability or because of the convenience of the Canadian pharmacies.

5) Other States. Seven states (Illinois, Minnesota, Nevada, Rode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites.

6) Previous Legislation. AB 73 (Frommer et.al. 2005) and AB 1957 (Frommer et.al. 2004), Drug Importation, are similar if not exact to importation provisions in AB 2877. AB 73 and AB 1957 both made it through the legislature and onto the Governor's desk; both bills were vetoed by the Governor. The board opposed AB 1957, as well as AB 73.

AB 74 (Gordon) California Rx Prescription Drug Hotline would have established a hotline that state residents could call for information about state and federal prescription drug discount programs. AB 74 was recently gutted and amended into a bill relating to the Butte County Healthy Communities Fund.

AB 308 (Baca) Purchasing Pool for Prescription Drugs, would have established a prescription drug purchasing pool that would allow employer health plans and the uninsured to join with state and local governments in the purchase of prescription drugs. AB 308 was gutted and amended into a bill relating to Military service, benefits. The measure was chaptered on September 22, 2005.

7) Support & Opposition to AB 73.

Support:

AIDS Healthcare Foundation
American Federation of State, County, and Municipal Employees
California Alliance of Retired Americans
California Federation of Teachers
California Labor Federation
California Medical Association
California Public Interest Research Group
California School Employees Association
California Teachers Association
City Council and City of Compton
Consumers Union
County of San Joaquin
Health Access California
Lieutenant Governor Cruz Bustamante
NAMI California
Older Women's League of California
Retired Public Employees Association
Senior Action Network
Service Employees International Union

Oppose:

BIOCOM
California Chamber of Commerce
California Health Institute
Pharmaceutical Research and Manufacturers of America

8) History.

2006

Apr. 6	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 15	Referred to Coms. on HEALTH and B. & P.
Feb. 27	Read first time.
Feb. 25	From printer. May be heard in committee March 27.
Feb. 24	Introduced. To print.

AMENDED IN ASSEMBLY APRIL 6, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 2877

Introduced by Assembly Member Frommer

February 24, 2006

An act to *amend Section 14982 of, and to repeal Section 14981 of, the Government Code, and to* add Article 5 (commencing with Section 110242) to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 2877, as amended, Frommer. Prescription drugs: importation: procurement.

~~Existing~~

(1) Existing law authorizes the Department of General Services to enter into exclusive or nonexclusive contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs. Existing law requires specified state agencies to participate in the prescription drug bulk purchasing program. Existing law requires the department to submit a report to the appropriate policy and fiscal committees of the Legislature on activities that have been, or will be, undertaken pursuant to these provisions.

This bill would, among other things, require the department to develop strategies for the state to achieve savings through greater use of generic drugs and would revise the report requirements.

(2) Existing law, the Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising

of food, drugs, devices, and cosmetics, under the administration of the State Department of Health Services.

Existing law, the Pharmacy Law, provides that any pharmacy located outside of this state that delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state is considered a nonresident pharmacy and requires a nonresident pharmacy to register with the California State Board of Pharmacy and comply with all lawful directions of, and requests for information from, the state in which it is a resident.

Existing federal law requires any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug that is imported or offered for import into the United States to register with the federal Secretary of Health and Human Services, report a list of each drug introduced for commercial distribution, and provide required information and statements.

This bill would establish the California RPrescription Drug Web Site Program. The bill would require the State Department of Health Services to administer the program and establish a Web site on or before July 1, 2007, to provide information to California residents about options for obtaining prescription drugs at affordable prices. The bill would, *except as specified,* require that the Web site, at a minimum, provide information about, and establish electronic links to, certain federal, state, and pharmaceutical programs, pharmacies that are located in Canada, the United Kingdom, and Ireland and that meet specified requirements, and other Web sites.

This bill would authorize the department to assess a fee on international pharmacies that the department reviews for possible inclusion on the Web site to offset the cost of reviewing those pharmacies. The bill would require the department's Web site to include price comparisons of prescription drugs, including prices charged by licensed pharmacies in the state and international pharmacies that provide mail-order service to the United States and whose Web sites are linked to the department's Web site.

This bill would also require the department to establish the California R Prescription Drug Hotline, on or before July 1, 2007, to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices. The bill would establish a maximum cost per call to the hotline and require the hotline to provide specific information.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Prescription drugs have become essential for ensuring the health of millions of Californians.

(b) The United States is the largest trade market for pharmaceuticals in the world, yet American consumers pay the highest prices for brand name pharmaceuticals in the world.

(c) Increased spending on prescription drugs is a significant driver of increases in overall health care costs, with spending nationwide on prescription drugs rising over 15 percent each year from 2000 to 2002.

(d) Rising out-of-pocket costs for prescription drugs are placing a growing burden on California consumers, as evidenced by federal government statistics that show that in 2002 the increase in consumers' out-of-pocket costs for prescription drugs was greater than the increase in out-of-pocket costs for all other health care expenditures.

(e) The price of brand name drugs is rising faster than the rate of inflation, with a recent study showing that the price of 30 drugs most frequently used by the elderly rose by over four times the rate of inflation in 2003 and that some drugs increased in price by 10 times the rate of inflation in that year.

(f) The rising cost of prescription drugs jeopardizes the health of seniors, the disabled, and other consumers who cannot afford the medication they need to stay healthy, as shown by a study by the RAND Corporation that found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over 20 percent and subsequently experienced higher rates of emergency room visits and hospital stays.

(g) The rising cost of prescription drugs places a disproportionate burden on communities of color, as shown in a report from the Center for Studying Health System Change that found that African-Americans are about 75 percent and Latinos

about 50 percent more likely than nonminorities to not have purchased a prescription drug in 2001 because of cost issues.

(h) A prescription drug is neither safe nor effective to an individual who cannot afford it.

(i) California residents face a growing need for assistance in finding information about sources for prescription drugs at affordable prices.

SEC. 2. Section 14981 of the Government Code is repealed.

~~14981. On or before February 1, 2005, the department shall submit a report to the appropriate policy and fiscal committees of the Legislature on activities that have been or will be undertaken pursuant to this chapter. The report shall include, but not be limited to, all of the following:~~

~~(a) The number and a description of contracts entered into with manufacturers and suppliers of drugs pursuant to Section 14977.1, including any discounts, rebates, or refunds obtained.~~

~~(b) The number and a description of entities that elect to participate in the coordinated purchasing program pursuant to Section 14977.5.~~

~~(c) Other options and strategies that have been or will be implemented pursuant to Sections 14978 and 14980.~~

~~(d) Estimated costs and savings attributable to activities that have been or will be undertaken pursuant to this chapter.~~

SEC. 3. Section 14982 of the Government Code is amended to read:

14982. (a) It is the intent of the Legislature that the Department of General Services, University of California, and the Public ~~Employees~~ *Employees'* Retirement System regularly meet and share information regarding each agency's procurement of prescription drugs in an effort to identify and implement opportunities for cost savings in connection with this procurement. It is the intent of the Legislature that the University of California and the Public ~~Employees~~ *Employees'* Retirement System cooperate with the department in order to reduce each agency's costs for prescription drugs.

(b) The department shall do all of the following:

(1) Share information on a regular basis with the University of California and the Public ~~Employees~~ *Employees'* Retirement System regarding each agency's procurement of prescription

drugs, including, but not limited to, prices paid for the same or similar drugs and information regarding drug effectiveness.

(2) Identify opportunities for the department, the University of California, and the Public ~~Employees~~ *Employees'* Retirement System to consolidate drug procurement or engage in other joint activities that will result in cost savings in the procurement of prescription drugs.

(3) Participate in at least one independent association that develops information on the relative effectiveness of prescription drugs.

(4) *Develop strategies, in consultation with the affected agencies, for the state to achieve savings through greater use of generic drugs.*

(5) No later than January 1, 2006, and annually thereafter, develop a work plan that includes, but is not limited to, a description of the department's annual activities to reduce the state's costs for prescription drugs and an estimate of cost savings.

~~(5)~~

(6) No later than January 10, 2006, and annually thereafter, report to the chairperson of the Joint Legislative Budget Committee and the chairs of the fiscal committees of the Legislature ~~on any joint activities of the department, the University of California, and the Public Employees Retirement System in the last 12 months in connection with procurement of prescription drugs and any resulting cost savings. This report shall include the work plan described in paragraph (4)~~ *and the appropriate fiscal committees of the Legislature on activities that have been, or will be, undertaken pursuant to this chapter. The report shall include, but not be limited to, all of the following:*

(A) The number and a description of contracts entered into with manufacturers and suppliers of drugs pursuant to Section 14977.1, including any discounts, rebates, or refunds obtained.

(B) The number and a description of entities that elect to participate in the coordinated purchasing program pursuant to Section 14977.5.

(C) A description of any joint activities of the department, the University of California, and the Public Employees' Retirement System in the last 12 months in connection with procurement of prescription drugs.

(D) Other options and strategies that have been or will be implemented pursuant to this chapter.

(E) Estimated costs and savings attributable to activities that have been, or will be, undertaken pursuant to this chapter.

(F) The work plan that the department is required to develop pursuant to paragraph (5).

(c) Nothing in this section shall be construed to require sharing of information that is prohibited by any other provision of law or contractual agreement, or the disclosure of information that may adversely affect potential drug procurement by any state agency.

~~SEC. 2.~~

SEC. 4. Article 5 (commencing with Section 110242) is added to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 5. California R Prescription Drug Web Site Program

110242. (a) The California R Prescription Drug Web Site Program is hereby established.

(b) The State Department of Health Services shall administer the program. The purpose of the program shall be to provide information to California residents and health care providers about options for obtaining prescription drugs at affordable prices.

(c) The department shall establish a Web site on or before July 1, 2007, which shall, at a minimum, provide information about, and electronic links to, all of the following:

(1) Prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program.

(2) State programs that provide drugs at discounted prices for California residents.

(3) Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.

(4) International pharmacies that provide mail-order service to the United States and who meet the requirements of paragraph (2) of subdivision (d). *If the federal government enacts, by October 15, 2006, procedures for individuals to obtain*

prescription drugs from international pharmacies, this paragraph shall not apply to the department Web site.

(5) Other Web sites as deemed appropriate by the department that help California residents to safely obtain prescription drugs at affordable prices, including links to Web sites of health plans and health insurers regarding their prescription drug formularies.

~~(d) (1) The Web site shall include price comparisons of at least 50 commonly prescribed brand name prescription drugs,~~

(d) (1) Unless the federal government enacts, by October 15, 2006, procedures for individuals to obtain prescription drugs from international pharmacies, the department's Web site shall include price comparisons of at least 150 commonly prescribed prescription drugs, including typical prices charged by licensed pharmacies in the state and by international pharmacies that provide mail-order service to the United States and whose Web sites are linked to the department's Web site pursuant to paragraph (2).

(2) The Web site shall provide information about, and establish electronic links to, pharmacies that are located in Canada, the United Kingdom, and Ireland that provide mail-order services to the United States and that meet all of the following requirements:

(A) Are licensed by the province or country, as appropriate, in which they are located.

(B) Comply with the requirements of a nonresident pharmacy as specified in Section 4112 of the Business and Professions Code, except that for purposes of this section all references to "state" in subdivision (d) of Section 4112 of the Business and Professions Code shall be deemed to refer to the province or other licensing jurisdiction in which the pharmacy is located. Compliance with this subparagraph shall be determined by the department in consultation with the California State Board of Pharmacy.

(C) Require a prescription from a patient's personal physician, who is licensed to practice in the United States.

(D) Require the completion of a relevant medical history profile.

(E) Require a signed patient agreement.

(F) Ship prescription drugs in tamperproof original manufacturer containers to individuals in the United States,

unless the consumer requests to receive the drug in a childproof container.

(G) Include a physical address and pharmacy license number on its company Web site.

(H) Do not furnish any of the following:

(i) A controlled substance.

(ii) A biological product, as defined in Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262).

(iii) An infused drug, including, a peritoneal dialysis solution.

(iv) An intravenously injected drug.

(v) A drug that is inhaled during surgery.

(vi) A drug that requires refrigeration or cannot be safely shipped by mail.

(vii) More than the prescribed amount of a drug or more than a three-month supply of any drug.

(viii) A drug that the consumer indicates he or she has not previously taken.

(ix) A drug for which there is no equivalent drug approved for sale in the United States by the federal Food and Drug Administration.

(I) Sell only prescription drugs that have been approved for sale in the country in which the pharmacy is located by the agency responsible for ensuring the safety of prescription drugs in that country.

(J) Comply with state law regarding the documentation of the pedigree of prescription drugs.

(K) Does not require a consumer to sign a waiver of liability or a release of liability for a negligent act by the pharmacy.

(L) Maintain a service department to respond to consumer inquiries and provide information to consumers about how they may file complaints with the provincial or other applicable licensing authority.

(M) Ensure that all physicians, pharmacists, and technicians in its employ are properly licensed and their licenses are in good standing.

(N) Comply with all personal health and medical information privacy laws applicable to pharmacies located in California.

(O) Any other requirement established by the department to ensure the safety, accessibility, and affordability of prescription drugs.

(3) A pharmacy that seeks to be linked to the department's Web site pursuant to paragraph (2) shall apply to the department. The department may enter into a contract with a pharmacy that it determines meets the requirements of paragraph (2). A contract may be renewed annually upon payment of the fee specified in paragraph (5) provided, that the pharmacy continues to comply with the requirements of paragraph (2).

(4) The department may terminate a contract with, and delete an electronic link to, or information about, a pharmacy that the department determines no longer complies with the requirements of paragraph (2). The department shall review within 30 business days any information that it receives regarding a pharmacy's compliance with the requirements of paragraph (2) and shall determine whether the information constitutes grounds for removal of the pharmacy from the Web site.

(5) The department may assess a fee on international pharmacies that the department reviews pursuant to paragraph (2) to offset the cost of reviewing those pharmacies.

(e) The department shall ensure that the Web site established pursuant to this section is coordinated with, and does not duplicate, other Web sites that provide information about prescription drug options and costs.

(f) Any information, including the identity of an international pharmacy, to be posted on the Web site shall first be approved by professional staff of the department before it is posted.

(g) The department shall include on the Web site a notice that informs consumers about state and federal laws governing the importation of prescription drugs and the federal Food and Drug Administration's policy governing personal importation. The notice shall also inform consumers that a pharmacy linked to the Web site is licensed in the country in which it is located and that the department has the right to remove a pharmacy from the Web site if it violates the requirements of paragraph (2) of subdivision (d) or the terms of any agreement between the department and the pharmacy. In addition, the notice shall include a statement that the state accepts no legal liability with respect to any product offered or pharmaceutical services provided by a pharmacy linked to the Web site.

110243. (a) The State Department of Health Services shall establish the California Rx Prescription Drug Hotline to provide

information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

(b) The department shall establish a low-cost 1-900 telephone number on or before July 1, 2007. Callers shall be provided information about options for obtaining prescription drugs at affordable prices. The cost per call to the hotline shall not exceed 50 cents ($0.50) and the hotline shall, at a minimum, provide the same type of information described in subdivision (c) of Section 110242.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2911 **VERSION: INTRODUCED**

AUTHOR: NUNEZ **SPONSOR: AUTHOR**

RECOMMENDED POSITION:

SUBJECT: CALIFORNIA DISCOUNT PRESCRIPTION DRUG PROGRAM

Existing Law:

Establishes within the Department of Health Services (DHS) a prescription drug discount program for Medicare recipients to enable recipients to obtain their prescription drugs at a cost no higher than the Medi-Cal reimbursement rates. (B&P 4425-4426)

This Bill:

1) Establishes the California Discount Prescription Drug Program (program) within DHS to use manufacturer rebates and pharmacy discounts to reduce prescription drug prices for eligible Californians. (H&S 130502 Added)

2) Defines the terms: department, eligible Californian, fund, manufacturer, manufacturer's rebate, multiple-source drug, national drug code, participating manufacturer, participating pharmacy, pharmacy contract rate, prescription drug, private discount drug program, program, therapeutic category. (H&S 130501 Added)

3) Establishes eligibility criteria for the program as a person that meets at least one of the following conditions:

i. A resident of the state whose total unreimbursed medical expenses equal 10 percent or more of family income and whose family income does not exceed 200 percent of the median family income in the state.

ii. An individual enrolled in Medicare who may participate in this program, to the extent allowed by federal law, for prescription drugs not covered by Medicare or with respect to an individual responsible for paying 100 percent of the cost of prescription drugs under the coverage gap provisions of the Medicare Program prescription drug benefit.

iii. A resident of the state who has a family income equal to or less than 350 percent of the federal poverty guidelines and does not have outpatient prescription drug coverage paid for in whole or in part by the Medi-Cal program, the Healthy Families Program, or other program funded by the state.

(H&S 130501 Added)

4) Permits DHS to contract with a third-party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi-Cal program's fiscal intermediary. (H&S 130541 Added)

5) Requires DHS or third party vendor to establish a Web site and call center to use for applying for the program. Additionally requires DHS or third party vendor to determine eligibility for the program within twenty-four hours of receipt of a completed application. (H&S 130520 Added)

6) Sets a fee of $10 for application to the program. (H&S 130520 Added)

7) Requires DHS to negotiate drug rebate agreements with drug manufacturer's to provide for discounts for prescription drugs purchased through the program; the first set of agreements would be in effect for no more than three years. (H&S 130506 Added)

8) Gives DHS additional authority and tools to negotiate lower net prices on prescription drugs if certain criteria are met. (H&S 130508 and 13509 Added)

9) Prohibits DHS from entering into a new contract or extend an existing contract with a drug manufacturer for the Medi-Cal program if the drug manufacturer does not provide to the California Discount Prescription Drug Program a rate comparable to or lower than the Medicaid best price. This prohibition would not apply to a drug for which there is no therapeutic equivalent. (H&S 13509 Added)

10) Sets the amount a recipient pays for a drug within program to be equal to the participating provider's usual and customary charge or the pharmacy contract rate, less a program discount for the specific drug or an average discount for a group of drugs or all drugs covered by the program. (H&S 130505 Added)

11) Permits DHS to conduct an outreach program to inform California residents of their opportunity to participate in program. (H&S 130521 Added)

12) Requires a drug dispensed pursuant to prescription to be accompanied by California Discount Prescription Drug Program participation information. Requires information to include advice to consult a health care provider or pharmacist about access to drugs at lower prices. Distribution of the information may be met by the distribution of a separate information form that is approved by, or produced and distributed by DHS. (H&S 1305022 Added)

13) Establishes the California Discount Prescription Drug Program Fund into which all payments received under the program would be deposited. The bill would continuously appropriate the fund to the DHS for purposes of the program. (H&S 130542 Added)

Comment:

1) Author's Intent. The author is concerned about the high cost of prescription drugs and the inability of uninsured individuals to pay for their medications.

2) Technical Problems with the Measure. There are two technical problems with the bill that relate to pharmacy law. The first problem is the definition of "prescription drug" in the measure. While the definition is similar to B&P 4022 definition of "dangerous drug," it is not exact. The difference in terms and definitions may create confusion among health care professionals and those involved in the program established by the bill. Rather than having two separate terms and definitions that are attempting to define the same thing, it might be best if AB 2911 were amended to delete the term "prescription drug" and in its place define "dangerous drug" as defined in B&P 4022.

The second problem with the bill is the requirement that information on the program be distributed with dispensed medications. The provision is not specific to drugs dispensed

through the program; as a result the provision implies that information is to be distributed with all medications dispensed in California. In 2004, approximately 260 million prescription drugs were filled at retail pharmacies in California. The provision as introduced is likely to be burdensome on California retail pharmacies. Additionally, the provision is in the Health and Safety Code so enforcement for the provision would be the responsibility of DHS, not the board.

3) Cost of Prescription Drugs and the Uninsured. In 2002, American consumers paid $48.6 billion in out-of-pocket costs for prescription drugs, an increase of 15 percent over the previous year. National prescription drug spending has increased at double-digit rates in each of the past eight years, and increased 15 percent from 2001 to 2002.

The rising cost of prescription drugs has had a harmful effect on the health of people who are dependent on those drugs. A recent study by the RAND Corporation found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over twenty percent and experienced higher rates of emergency room visits and hospital stays.

Those who are uninsured for prescription drugs also suffer. A recent survey found that thirty-seven percent of the uninsured said that they did not fill a prescription because of cost, compared to 13 percent of the insured. A 2001 survey of seniors found that in the previous 12 months, 35 percent of seniors without prescription drug coverage either did not fill a prescription or skipped doses in order to make the medicine last longer.

4) State Strategies for Reducing Cost of Drugs. Across the US two strategies have emerged at the state level to reduce the cost of prescription drugs for consumers.

The first strategy is to facilitate the importation of drugs from outside the US, primarily from Canada or the UK. Six states (Illinois, Minnesota, Rode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites. Additionally, 20 or more states, including California, have legislation pending to create either a Web site or phone line that would provide information on importing drugs from Canada.

The second strategy is to create drug discount programs. As of February 2005 at least 39 states have established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Most programs utilize state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria, but an increasing number (22 states) have created or authorized programs that offer a discount only (no subsidy) programs for eligible or enrolled seniors; a majority of these states also have a separate subsidy program.

5) Previous Legislation. Two bills, AB 75 and SB 19, were introduced in 2005 that would have established a drug discount program in California. Language similar to both bills was placed on the November 8, 2005 ballot in the form of Propositions (Proposition 79 and Proposition 78). Voters voted down both propositions.

AB 75 (Frommer) Pharmaceutical Assistance Program, would establish the California Rx Plus State Pharmacy Assistance Program within DHS. AB 75 requires DHS to negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program. The measure establishes eligibility for the program for families with incomes equal to or less than 400 percent of the federal poverty guidelines. AB 75 is a two-year bill, however it is unlikely the bill will move forward this session.

SB 19 (Ortiz) California Rx Program was introduced last year and sponsored by the Governor. SB 19 would have established a state program to negotiate for lower price prescription drugs for lower income Californians. SB 19 failed to make it out of the Senate and is dead for the legislative session.

6) **History.**

2006

Mar. 23	Referred to Com. on HEALTH.
Feb. 27	Read first time.
Feb. 25	From printer. May be heard in committee March 27.
Feb. 24	Introduced. To print.

ASSEMBLY BILL No. 2911

Introduced by Assembly Member Nunez
(Coauthor: Senator Perata)

February 24, 2006

An act to add Division 112 (commencing with Section 130500) to the Health and Safety Code, relating to pharmacy assistance, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 2911, as introduced, Nunez. California Discount Prescription Drug Program.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufacturers are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California Discount Prescription Drug Program within the department. The bill would require the department to negotiate drug discount agreements with drug manufacturers and pursue manufacturer rebate agreements for drugs in each therapeutic category. The bill would authorize any licensed pharmacy and any drug manufacturer, as defined, to participate in the program. The bill would establish eligibility criteria and application procedures for eligible Californians to participate in the program. The application process would require an applicant to attest to information provided under penalty of perjury, which would expand the definition of an existing crime, thereby imposing a state-mandated local program.

The bill would establish the California Discount Prescription Drug Program Fund into which all payments received under the program would be deposited. The bill would continuously appropriate the fund to the department for purposes of the program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: $\frac{2}{3}$. Appropriation: yes. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. The Legislature hereby finds and declares all of the following:

(a) The people of California find that affordability is critical in providing access to prescription drugs for California residents, particularly the uninsured and those with inadequate insurance.

(b) The California Discount Prescription Drug Program is enacted by the people to enable the state to take steps to make prescription drugs more affordable for qualified California residents, thereby increasing the overall health of California residents, promoting healthy communities, and protecting the public health and welfare.

(c) It is not the intent of the state to discourage employers from offering or paying for prescription drug benefits for their employees or to replace employer-sponsored prescription drug benefit plans that provide benefits comparable to those made available to qualified California residents under this program.

SEC. 2. Division 112 (commencing with Section 130500) is added to the Health and Safety Code, to read:

DIVISION 112. CALIFORNIA DISCOUNT PRESCRIPTION DRUG PROGRAM

CHAPTER 1. GENERAL PROVISIONS

130500. This division shall be known, and may be cited, as the California Discount Prescription Drug Program.

130501. For purposes of this division, the following definitions shall apply:

(a) "Department" means the State Department of Health Services.

(b) "Eligible Californian" means any one or more of the following:

(1) A resident of the state whose total unreimbursed medical expenses equal 10 percent or more of family income and whose family income does not exceed 200 percent of the median family income in the state.

(2) An individual enrolled in Medicare who may participate in this program, to the extent allowed by federal law, for prescription drugs not covered by Medicare or with respect to an individual responsible for paying 100 percent of the cost of prescription drugs under the coverage gap provisions of the Medicare Program prescription drug benefit.

(3) A resident of the state who has a family income equal to or less than 350 percent of the federal poverty guidelines and does not have outpatient prescription drug coverage paid for in whole or in part by the Medi-Cal program, the Healthy Families Program, or other program funded by the state.

(4) For purposes of this subdivision, the cost of drugs provided under this division is considered an expense incurred by the family for eligibility determination purposes.

(c) "Fund" means the California Discount Prescription Drug Program Fund.

(d) "Manufacturer" means a drug manufacturer as defined in Section 4033 of the Business and Professions Code.

(e) "Manufacturer's rebate" means the rebate for an individual drug or aggregate rebate for a group of drugs necessary to make the price for the drug ingredients equal to or less than the applicable benchmark price.

(f) "Multiple-source drug" means the same drug in the same dosage form and strength manufactured by two or more manufacturers, which is approved by the United States Food and Drug Administration under provisions pertaining to the Abbreviated New Drug Applications (ANDA) process.

(g) "National Drug Code" or "NDC" means the unique 10-digit, three-segment number assigned to each drug product listed under Section 510 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360). This number identifies the labeler or vendor, product, and trade package.

(h) "Participating manufacturer" means a drug manufacturer that has contracted with the department to provide an individual drug or group of drugs for the program.

(i) "Participating pharmacy" means a pharmacy that has executed a pharmacy provider agreement with the department for this program.

(j) "Pharmacy contract rate" means the negotiated per prescription reimbursement rate for drugs dispensed to eligible Californians.

(k) "Prescription drug" means any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(l) "Private discount drug program" means a prescription drug discount card or manufacturer patient assistance program that provides discounted or free drugs to eligible individuals. For the purposes of this division, a private discount drug program is not considered insurance or a third-party payer program.

(m) "Program" means the California Discount Prescription Drug Program.

(n) "Therapeutic category" means a drug or a grouping of drugs determined by the department to have similar attributes and to be alternatives for the treatment of a specific disease or condition.

130502. The California Discount Prescription Drug Program is hereby established within the State Department of Health Services to use manufacturer rebates and pharmacy discounts to reduce prescription drug prices for Californians. The purpose of the program is to reduce prescription drug prices and improve the quality of health care for eligible Californians.

CHAPTER 2. PRESCRIPTION DRUG DISCOUNTS

130505. (a) The amount a participating, eligible Californian pays for a drug through the program shall be equal to the participating provider's usual and customary charge or the pharmacy contract rate pursuant to subdivision (c), less a program discount for the specific drug or an average discount for a group of drugs or all drugs covered by the program.

(b) In determining program discounts on individual drugs, the department shall take into account the rebates provided by the drug's manufacturer and the state's share of the discount.

(c) The department may contract with participating pharmacies for a rate other than the pharmacies' usual and customary rate.

130506. (a) The department shall negotiate drug discount agreements with drug manufacturers to provide for discounts for prescription drugs purchased through this program. The department shall pursue manufacturer rebate agreements for drugs in each therapeutic category.

(b) The department shall attempt to obtain discounts for eligible Californians that on an average equal or exceed 50 percent of the list price, or that average 80 percent of the lowest wholesale acquisition cost price, for a drug published by a wholesaler in the state generally available to the retail class of trade in the state.

(c) To obtain the most favorable discounts, the department may limit the number of drugs available through the program.

(d) The drug rebate agreements negotiated pursuant to this section shall be used to reduce the cost of drugs purchased by program participants.

(e) (1) Any pharmacy licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code may participate in the program.

(2) Any drug manufacturer may participate in the program.

130507. (a) The department shall attempt to negotiate drug discount agreements with drug manufacturers for a period not to exceed three years from January 1, 2007. At that time, the department shall make a determination as to whether:

(1) The number and type of drugs available through the program is sufficient to give eligible Californians a formulary

comparable to that provided to Medi-Cal beneficiaries or, if this information is available to the department, a formulary comparable to that provided to CalPERS enrollees.

(2) The discounts for the drugs on an average equal or exceed the threshold in subdivision (b) of Section 130506.

(3) Manufacturer participation has been sufficient to provide discounts on a range of drugs consistent with this section.

(b) If the department determines that any one of the thresholds in this section is not met, then the department shall implement Sections 130508 and 130509.

130508. (a) Consistent with federal law, the department shall seek to contract for that result in a net price comparable to or lower than the Medicaid best price for drugs covered by the California Discount Prescription Drug Program. The department shall also seek to contract a net price comparable to or lower than the price for prescription drugs provided to the federal government.

(b) The department shall seek a state plan amendment that maximizes the number of eligible Californians able to receive discounts consistent with this section.

(c) If the federal Centers for Medicare and Medicaid Services deny approval of a state plan amendment or federal waiver for any Californians eligible under state law for drug discounts, then the department shall continue to operate a discount drug program for these persons consistent with Section 130507. To the maximum extent possible, the department shall assure that enrollment and other administrative actions are seamless to all eligible Californians, whether the eligible Californian is enrolled in a program administered consistent with this section or with Section 130507.

130509. (a) Subject to this section, the department shall not enter into a new contract or extend an existing contract with a drug manufacturer for the Medi-Cal program if the drug manufacturer does not provide to the California Discount Prescription Drug Program a rate comparable to or lower than the Medicaid best price. This prohibition shall not apply to a drug for which there is no therapeutic equivalent.

(b) To the extent permitted by federal law, the department may require prior authorization in the Medi-Cal program for any drug of a manufacturer that fails to agree to a price comparable to or

lower than the Medi-Cal best price for prescription drugs purchased under this division.

(c) If a contract with a manufacturer is prohibited by subdivision (a) or if prior authorization is required for a drug pursuant to this section, a Medi-Cal beneficiary shall not be denied the continued use of a drug that is part of a prescribed therapy until that drug is no longer prescribed for that beneficiary's therapy. The department shall approve or deny requests for prior authorization necessitated by this section as required by state or federal law.

(d) This section shall be implemented in a manner consistent with federal law.

130510. The names of manufacturers that do or do not enter into rebate agreements with the department pursuant to this division shall be public information, shall be released to the public, and shall be posted on the department's Internet Web site at the time when the rebate agreements are reached, commencing within six months after the initial implementation date of this article and updated on the first of each month thereafter.

130511. (a) Each drug rebate agreement shall do all of the following:

(1) Specify which of the manufacturer's drugs are included in the agreement.

(2) Permit the department to remove a drug from the agreement if there is a dispute over the drug's utilization.

(3) Require the manufacturer to make a rebate payment to the department for each drug specified under paragraph (1) dispensed to a program participant.

(4) Require the manufacturer to make the rebate payments to the department on at least a quarterly basis.

(5) Require the manufacturer to provide, upon the request of the department, documentation to validate the rebate.

(6) Permit a manufacturer to audit claims for the drugs the manufacturer provides under the program. Claims information provided to manufacturers shall comply with all federal and state privacy laws that protect a program participant's health information.

(b) The department may collect prospective rebates from manufacturers for payment to pharmacies. The amount of the

prospective rebate shall be specified in the drug rebate agreements.

(c) (1) Manufacturers shall calculate and pay interest on late or unpaid rebates. The interest shall not apply to any prior period adjustments of unit rebate amounts or department utilization adjustments.

(2) For state rebate payments, manufacturers shall calculate and pay interest on late or unpaid rebates for quarters that begin on or after January 1, 2007.

(d) Interest required by subdivision (c) shall begin accruing 38 calendar days from the date of mailing of the invoice, including supporting utilization data sent to the manufacturer. Interest shall continue to accrue until the date of mailing of the manufacturer's payment. Interest rates and calculations for purposes of this section shall be at ____ percent.

(e) A participating manufacturer shall clearly identify all rebates, interest, and other payments, and payment transmittal forms for the program, in a manner designated by the department.

130512. (a) The department shall generate a monthly report that, at a minimum, provides all of the following:

(1) Drug utilization information.

(2) Amounts paid to pharmacies.

(3) Amounts of rebates collected from manufacturers.

(4) A summary of the problems or complaints reported regarding the program.

(b) Information provided in paragraphs (1), (2), and (3) of subdivision (a) shall be at the national drug code level.

130513. (a) The department shall establish and maintain a claims processing system that complies with all of the following requirements:

(1) Charges a price that meets the requirements of this division.

(2) Provides the pharmacy with the dollar amount of the discount to be returned to the pharmacy.

(3) Provides drug utilization review warnings to pharmacies consistent with the drug utilization review standards provided in federal law.

(b) The department shall pay a participating pharmacy the discount provided to program participants pursuant to this

division by a date that is not later than two weeks after the claim is received.

(c) The department shall develop a mechanism for the program participants to report problems or complaints.

CHAPTER 3. APPLICATION, ENROLLMENT, AND OUTREACH

130520. (a) The department shall develop an application and reapplication form for the determination of a resident's eligibility for the program. An applicant, or a guardian or custodian of an applicant, may apply or reapply on behalf of the applicant and the applicant's spouse and children.

(b) The application shall, at a minimum, do all of the following:

(1) Specify the information that an applicant or the applicant's representative must include in the application.

(2) Require that the applicant, or the applicant's guardian or custodian, attest that the information provided in the application is accurate to the best knowledge and belief of the applicant or the applicant's guardian or custodian.

(3) Specify that the application fee due upon submission of the applicable form is ten dollars ($10).

(c) In assessing the income requirement for eligibility, the department shall use the income information reported on the application and not require additional documentation.

(d) An application may be completed at any pharmacy, physician office, or clinic participating in the program through an Internet Web site or call center staffed by trained operators approved by the department. A pharmacy, physician's office, clinic, or nonprofit community organization that completes the application shall keep the application fee as reimbursement for its processing costs. If it is determined that the applicant is already enrolled in the program, the fee shall be returned to the applicant and the applicant shall be informed of his or her current status as a program participant.

(e) The department shall utilize a secure electronic application process that can be used by a pharmacy, physician's office, or clinic, by an Internet Web site, by a call center staffed by trained operators, by a nonprofit community organization, or through the third-party vendor to enroll applicants in the program.

(f) During the department's normal working hours, the department shall make a determination of eligibility within 24 hours of receipt by the program of a completed application. The department shall mail the program participant an identification card no later than seven days after eligibility has been determined.

(g) For applications submitted through a pharmacy, the department may issue a participant identification number for eligible applicants to the pharmacy for immediate access to the California Discount Prescription Drug Program.

(h) Any program participant that has been determined to be eligible shall be enrolled for 12 months, which ever occurs first or until the program participant notifies the department of an intent to end enrollment.

(i) The department shall notify a program participant of termination of enrollment 30 days prior to the termination. A program participant shall remain enrolled in the program until the participant notifies the department that the participant no longer meets the eligibility criteria.

(j) A person shall be required to apply pursuant to this section for each 12-month period of eligibility.

130521. (a) The department may conduct an outreach program to inform California residents of their opportunity to participate in the program. The department shall coordinate outreach activities with the California Department of Aging and other state and local agencies, and nonprofit organizations that serve residents who may be eligible for the program. No outreach material shall contain the name or likeness of a drug.

(b) The department may accept on behalf of the state any gift, bequest, or donation of outreach services or materials to inform residents about the program. The name of the organization sponsoring the materials shall in no way appear on the material but shall be reported to the public and the Legislature as otherwise provided by law.

130522. (a) A drug dispensed pursuant to prescription, including a drug dispensed without charge to the consumer, shall be accompanied by the California Discount Prescription Drug Program participation information in a manner approved by the department and as permitted by law.

(b) The information shall include advice to consult a health care provider or pharmacist about access to drugs at lower prices.

(c) The requirements of this section may be met by the distribution of a separate information form that is approved by, or produced and distributed by, the department.

CHAPTER 4. PHARMACEUTICAL MANUFACTURER PATIENT ASSISTANCE PROGRAMS

130530. (a) The department shall encourage a participating manufacturer to maintain those private discount drug programs that are comparable to or more extensive than those provided prior to the enactment of this division. To the extent possible, the department shall encourage a participating manufacturer to simplify the application and eligibility processes for its private discount drug program.

(b) The department shall execute agreements with drug manufacturers and other private patient assistance programs to provide a single point of entry for eligibility determination and claims processing for drugs available through those programs.

(c) The department shall develop a system to provide a program participant under this division with the best discounts on prescription drugs that are available to the participant through this program or through a drug manufacturer or other private patient assistance program.

(d) (1) The department may require an applicant to provide additional information to determine the applicant's eligibility for other discount card and patient assistance programs.

(2) The department shall not require an applicant to participate in a drug manufacturer patient assistance program or to disclose information that would determine the applicant's eligibility to participate in a drug manufacturer patient assistance program in order to participate in the California Discount Prescription Drug Program.

(e) In order to verify that California residents are being served by drug manufacturer patient assistance programs, the department shall require drug manufacturers to provide the department annually with all of the following information:

(1) The total value of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(2) The total number of prescriptions or 30-day supplies of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(f) The California Discount Prescription Drug Program card issued pursuant to this division shall serve as a single point of entry for drugs available pursuant to subdivision (a), and shall meet all legal requirements for a health benefit card.

CHAPTER 5. ADMINISTRATION

130540. Contracts entered into for purposes of this division are exempt from Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code. Contracts with pharmacies and drug manufacturers may be entered into on a bid or nonbid basis.

130541. To implement the program, the department may contract with a third-party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi-Cal program's fiscal intermediary. Drug rebate contracts negotiated by a third party shall be subject to review by the department. The department may cancel a contract that it finds not in the best interests of the state or program participants.

130542. (a) The department shall deposit all payments the department receives pursuant to this division into the California Discount Prescription Drug Program Fund, which is hereby established in the State Treasury.

(b) Notwithstanding Section 13340 of the Government Code, the fund is hereby continuously appropriated to the department without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to this division and for defraying the costs of administering this division. Notwithstanding any other provision of law, no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund. The fund shall also contain any interest accrued on moneys in the fund.

130543. (a) (1) The director may adopt regulations as are necessary for the initial implementation of this division. The adoption, amendment, repeal, or readoption of a regulation authorized by this section is deemed to be necessary for the

immediate preservation of the public peace, health and safety, or general welfare, for purposes of Sections 11346.1 and 11349.6 of the Government Code, and the department is hereby exempted from the requirement that it describe specific facts showing the need for immediate action.

(b) As an alternative to the adoption of regulations pursuant to subdivision (a), and notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the director may implement this division, in whole or in part, by means of a provider bulletin or other similar instructions, without taking regulatory action, provided that no bulletin or other similar instructions shall remain in effect after July 31, 2007. It is the intent that regulations adopted pursuant to this subdivision shall be in place on or before July 31, 2007.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

AMENDED IN ASSEMBLY MARCH 28, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

Assembly Joint Resolution No. 40

Introduced by Assembly Members Chan and Berg
(Coauthors: Assembly Members Cohn, Lieu, and Mullin)

January 19, 2006

Assembly Joint Resolution No. 40—Relative to Medicare prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AJR 40, as amended, Chan. Medicare prescription drugs.

This measure would memorialize the United States Congress and President to enact H.R. No. 3861, "The Medicare Informed Choice Act of 2005."

Fiscal committee: no.

WHEREAS, The United States Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) in 2003; and

WHEREAS, The MMA promised a voluntary prescription drug benefit, known as Medicare Part D, to all Medicare beneficiaries; and

WHEREAS, At the insistence of Congress and the President of the United States, Part D is administered by multiple private insurance companies offering dozens of different plans in every state; and

WHEREAS, In California alone, Medicare beneficiaries who wish to enroll in Part D must choose from 47 different

stand-alone Medicare prescription drug plans and many more Medicare Advantage plans; and

WHEREAS, On October 15, 2005, Medicare prescription drug plan sponsors began aggressively marketing their plans to seniors and persons with disabilities; and

WHEREAS, On November 15, 2005, Medicare beneficiaries throughout the country began enrolling in the new Medicare Part D prescription drug plans; and

WHEREAS, As of December 2005, only 1 million of the approximately 21 million Medicare beneficiaries throughout the country who are eligible for voluntary enrollment in Part D had enrolled; and

WHEREAS, In addition only a small percentage of the millions of low-income beneficiaries eligible for federal subsidies have enrolled in Part D; and

WHEREAS, Federal law currently requires the initial open enrollment period to end on May 15, 2006, after, which Medicare beneficiaries will be subject to substantial permanent financial penalties for "late enrollment"; and

WHEREAS, The structure of Part D and the need to choose from among dozens of plans are causing confusion and consternation among seniors; and

WHEREAS, There have not been enough independent counselors available to help guide seniors through the myriad options; and

WHEREAS, Seniors who currently have retiree health care coverage, including prescription drug coverage, are at risk of losing both their existing health and drug coverage if they inadvertently enroll in Medicare Part D; and

WHEREAS, The federal government should not penalize seniors for being confused, but should work to provide Medicare beneficiaries the time and opportunity to make the best choice about their prescription drug coverage; and

WHEREAS, Legislation has been introduced in the Congress, H.R. No. 3861, "The Medicare Informed Choice Act of 2005", that extends the deadline for enrollment in Medicare Part D until December 31, 2006, permits Medicare beneficiaries to change plans once in 2006 if they have made a poor selection, and protects those with retiree health benefits who may not be aware

that purchasing Medicare drug coverage could cost them their retiree benefits; now, therefore, be it

Resolved by the Assembly and the Senate of the State of California, jointly, That the Legislature of the State of California memorializes the Congress and the President of the United States to enact H.R. No. 3861, "The Medicare Informed Choice Act of 2005" to ~~protect~~ *give* our nation's disabled and senior citizens who are Medicare ~~beneficiaries;~~ *beneficiaries the time to make an informed decision and protect them from losing their retiree health benefits;* and be it further

Resolved, That the Chief Clerk of the Assembly transmit copies of this resolution to the President of the United States and to all Member of the Congress of the United States.

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Assembly Joint Resolution No. 49

Introduced by Assembly Member Nation

March 29, 2006

Assembly Joint Resolution No. 49—Relative to pharmaceutical advertisements.

LEGISLATIVE COUNSEL'S DIGEST

AJR 49, as introduced, Nation. Direct-to-consumer prescription drug advertisements.

This measure would request that the United States Food and Drug Administration aggressively monitor and regulate direct-to-consumer advertising of prescription drugs by pharmaceutical companies, and would memorialize the President and the Congress to ~~limit~~ *ban* that advertising~~, unless certain conditions are met~~.

Fiscal committee: no.

WHEREAS, The United States is one of just a few countries that allow pharmaceutical companies to advertise prescription drugs; and

WHEREAS, Direct-to-consumer prescription drug advertising is a category of promotional information about specific drug treatments that is provided directly to consumers by or on behalf of drug companies; and

WHEREAS, Direct-to-consumer prescription drug advertising is not necessary in order for pharmaceutical companies to sell their products; and

WHEREAS, Since pharmaceutical companies have been allowed to broadcast advertisements that mention a prescription

drug by name without disclosing all of the risks of that medication, consumer demand for prescription medications has increased, resulting in a corresponding increase in the cost of prescriptions and of health care delivery; and

WHEREAS, While the pharmaceutical community has tried to convince the public, Congress, and the United States Food and Drug Administration (hereafter the FDA) that direct-to-consumer prescription drug advertisements are educational, rather than promotional, the actual goal of the advertisements is not to educate the public, but rather to ensure that patients walk out of their doctors' offices with a prescription for a particular brand of prescription drug, rather than with a prescription for a competitor's product or some other form of therapy that better suits the patient; and

WHEREAS, Physicians are under increasing pressure from patients who suspect that Heath Maintenance Organization formularies restrict physicians from prescribing the best prescription drugs; and

WHEREAS, Direct-to-consumer advertising of prescription drugs forces physicians to spend valuable time defending the reason that an advertised drug is unnecessary or detrimental to the patient's health; and

WHEREAS, If a physician declines to issue a prescription for a drug that a patient has seen advertised, the patient may turn to other sources to obtain the drug, including the Internet; and

WHEREAS, According to the United States General Accounting Office, the investigational arm of Congress, pharmaceutical manufacturers spent $1.1 billion in 1997 on direct-to-consumer prescription drug advertising, which increased to $2.7 billion in 2001, with expenditures increasing by double digits every year; and

WHEREAS, Numerous studies have linked the increased direct-to-consumer prescription drug advertising to the exponential growth in prescription drug expenditures; and

WHEREAS, In 1997, the FDA relaxed restrictions on the content of direct-to-consumer prescription drug advertising, withdrawing the prior requirement of a summary of side-effect and adverse reaction information and replacing it with a requirement for a statement about "major risks" but not "all

risks," which made television and radio advertisements about prescription drugs more practicable; now, therefore, be it

Resolved by the Assembly and the Senate of the State of California, jointly, That the United States Food and Drug Administration is requested to aggressively monitor and regulate direct-to-consumer advertising of prescription drugs by pharmaceutical companies, pending action by the President and the Congress of the United States to limit, ban, or place increased restrictions on that advertising; and be it further

Resolved, That the President and the Congress of the United States are memorialized to ban direct-to-consumer advertising of prescription drugs by pharmaceutical companies; and be it further

Resolved, That the Chief clerk of the Assembly transmit copies of this resolution to the President of the United States, to the Speaker of the House of Representatives, to the Majority Leader of the Senate, to each Senator and Representative from California in the Congress of the United States, to the Secretary of the United States Department of Health and Human Services, and to the Director of the United States Food and Drug Administration.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1305 **VERSION: AMENDED MARCH 29, 2006**

AUTHOR: FIGUEROA **SPONSOR: AUTHOR**

RECOMMENDED POSITION:

SUBJECT: THE MEDICAL WASTE MANAGEMENT ACT

Existing Law:

1) Defines "sharps waste" as waste generated by a household that includes a hypodermic needle, syringe, or lancet. (Public Resources Code 40190.5)

Related Law Law:

1) Allows counties and cities to establish a Disease Prevention Demonstration Project (DPDP), that allows certified pharmacies to sell of up to 10 hypodermic needles to individuals over 18 years of age without a prescription. Pharmacies that participate in a DPDP are required to provide one or more of the following options for the safe disposal of hypodermic needle:

i. Have an onsite safe hypodermic needle and syringe collection and disposal program.
ii. Furnish or make available for purchase mail-back sharps disposal containers authorized by the United States Postal Service that meet applicable state and federal requirements, and provide tracking forms to verify destruction at a certified disposal facility.
iii. Furnish or make available for purchase personal sharps disposal containers that meet state and federal standards for disposal of medical waste.

(H&S 121285)

This Bill:

1) Defines "home-generated sharps waste" as hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications derived from a household, including a multifamily residence or household.
(H&S 117671 Added)

2) Excludes “home-generated sharps waste” from the definition of medical waste.
(H&S 117700 Amended)

3) Prohibits a person on or after January 1, 2008, from knowingly placing home-generated sharps waste in any of the following containers:

i. Any container used for the collection of solid waste, recyclable materials, or greenwaste.
ii. Any container used for the commercial collection of solid waste or recyclable materials from business establishments.

iii. Any roll-off container used for the collection of solid waste, construction, and demolition debris, greenwaste, or other recyclable materials. (H&S 118286 Added)

4) Requires on or after January 1, 2008, home-generated sharps waste to be transported only in a sharps container, or other approved containers, and to only be managed at any of the following:

i. A household hazardous waste facility.

ii. A home-generated sharps consolidation point.

iii. A medical waste generator's facility.

iv. A facility, through the use of a medical waste mail-back container, approved by the Department of Health Services.

(H&S 118286)

Comment:

1) Author's Intent. The author's intent is to close a loophole in current law that allows home-generated needles to be legally placed in solid waste and recycling containers where they present substantial risks to workers and the general public. Currently fifty percent of counties accept sharps at their county waste disposal sites; often times the collection of sharps at the sites is funded through waste collection or utility tax funds. The author is looking for a solution to this problem that may include manufacturers taking back used sharps that have been paid for by health insurance.

2) Problems as Currently Written. There are a couple problems with the bill. The first problem is the bill is unenforceable. The bill would prohibit people from disposing of sharps in "garbage cans," green waste or recycling collection containers. Much like the disposable battery law that recently took effect on January 1, 2006 that would prohibit a person from disposing of batteries in their household waste; there is no reasonable way for a city or county to monitor peoples disposal habits and enforce the law.

The second problem with the bill is in the absence of funding from government or industry, the bill could prove costly to people who use sharps. The bill does not specify how sharps will move from an individual's home to an approved facility or who is responsible for providing approved sharps containers. It is conceivable that a sharps user could be responsible for both the costs of the sharps containers as well as transport of the sharps. Finding a source of funding for disposal other than sharps users will likely result in a higher rate of compliance with the law.

3) Previous Legislation.

SB 1159 (Chapter 608, Statutes of 2004) allows counties and cities to establish a Disease Prevention Demonstration Project (DPDP), that allows certified pharmacies to sell of up to 10 hypodermic needles to individuals over 18 years of age without a prescription. The measure also requires participating pharmacies to provide one of three options for the safe disposal of hypodermic needles.

SB 1362 (Chapter 157, Statutes of 2004) established the Safe Needle Disposal Act of 2004, allows, but does not mandate cities and counties to authorize household hazardous waste (HHW) collection facilities to operate as home-generated sharps consolidation points. Additionally, the measure defined "sharps waste" in Public Resources Code section 40190.5.

SB 372 (Chapter 877, Statutes of 1995) authorized, but did not mandate 1) a medical waste generator to accept home-generated sharps waste for consolidation with its own medical wastes and 2) an enforcement agency to approve a location as a point of consolidation for the collection of home-generated sharps waste, which would be required to be transported and treated as medical waste.

4) History.

2006

Apr. 3	Set, first hearing. Hearing canceled at the request of author. Set for hearing April 17.
Mar. 29	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 20	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 13	Set for hearing April 3.
Feb. 22	To Com. on E.Q.
Feb. 17	From print. May be acted upon on or after March 19.
Feb. 16	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE MARCH 29, 2006

AMENDED IN SENATE MARCH 20, 2006

SENATE BILL No. 1305

Introduced by Senator Figueroa

February 16, 2006

An act to *amend Section 117700 of, and to* add Sections 117671 and 118286 to, the Health and Safety Code, relating to medical waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 1305, as amended, Figueroa. ~~Medical waste.~~ *The Medical Waste Management Act.*

The existing Medical Waste Management Act, administered by the State Department of Health Services, regulates the management and handling of medical waste, as defined. ~~The act is enforced by the department and local enforcement agencies.~~ *Under existing law, certain items, such as household waste, are specifically excluded from the definition of medical waste.*

This bill would also exclude home-generated sharps waste, as defined, from the definition of medical waste.

Existing law permits a registered medical waste generator, if specified conditions are met, to accept home-generated sharps waste to be consolidated with the facility's medical waste stream.

Existing law also permits a household hazardous waste collection facility, if specified conditions are met, to operate a home-generated sharps consolidation point, and permits the department to approve other home-generated sharps consolidation points.

This bill would specifically define home-generated sharps waste.

This bill would, on or after January 1, 2008, prohibit a person from knowingly placing home-generated sharps waste in certain types of

containers, provide that home-generated sharps waste shall be transported only in a sharps container, as defined in the act, or other container approved by the department or local enforcement agency, and provide that this waste shall only be managed at specified locations consistent with existing law.

~~Since a violation of an order enforcing the Medical Waste Management Act is a misdemeanor, the bill would impose a state-mandated local program.~~

~~The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.~~

~~This bill would provide that no reimbursement is required by this act for a specified reason.~~

Vote: majority. Appropriation: no. Fiscal committee: ~~yes~~ *no*. State-mandated local program: ~~yes~~ *no*.

The people of the State of California do enact as follows:

SECTION 1. Section 117671 is added to the Health and Safety Code, to read:

117671. "Home-generated sharps waste" means hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications derived from a household, including a multifamily residence or household.

SEC. 2. Section 117700 of the Health and Safety Code is amended to read:

117700. Medical waste does not include any of the following:

(a) Waste generated in food processing or biotechnology that does not contain an infectious agent as defined in Section 117675.

(b) Waste generated in biotechnology that does not contain human blood or blood products or animal blood or blood products suspected of being contaminated with infectious agents known to be communicable to humans.

(c) Urine, feces, saliva, sputum, nasal secretions, sweat, tears, or vomitus, unless it contains fluid blood, as provided in subdivision (d) of Section 117635.

(d) Waste which is not biohazardous, such as paper towels, paper products, articles containing nonfluid blood, and other medical solid waste products commonly found in the facilities of medical waste generators.

(e) Hazardous waste, radioactive waste, or household waste, *including, but not limited to, home-generated sharps waste, as defined in Section 117671.*

(f) Waste generated from normal and legal veterinarian, agricultural, and animal livestock management practices on a farm or ranch.

~~SEC. 2.~~

SEC. 3. Section 118286 is added to the Health and Safety Code, to read:

118286. (a) On or after January 1, 2008, no person shall knowingly place home-generated sharps waste in any of the following containers:

(1) Any container used for the collection of solid waste, recyclable materials, or greenwaste.

(2) Any container used for the commercial collection of solid waste or recyclable materials from business establishments.

(3) Any roll-off container used for the collection of solid waste, construction, and demolition debris, greenwaste, or other recyclable materials.

(b) On or after January 1, 2008, home-generated sharps waste shall be transported only in a sharps container, or other containers approved by the enforcement agency, and shall only be managed at any of the following:

(1) A household hazardous waste facility pursuant to Section 25218.13.

(2) A "home-generated sharps consolidation point" as defined in subdivision (b) of Section 117904.

(3) A medical waste generator's facility pursuant to Section 118147.

(4) A facility through the use of a medical waste mail-back container approved by the department pursuant to subdivision (b) of Section 118245.

~~SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or~~

~~infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.~~

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1430 **VERSION: AMENDED MARCH 28, 2006**

AUTHOR: ALQUIST **SPONSOR: HEALTH OFFICERS ASSOCIATION OF CALIFORNIA**

RECOMMENDED POSITION:

SUBJECT: THE LOCAL PANDEMIC AND EMERGENCY HEALTH PREPAREDNESS ACT OF 2006

Existing Law:

1) Gives county health officers broad powers to prevent the spread of a communicable disease once a case appears in her or his jurisdiction.

2) Prohibits a health care, health care service plan, or contractor from disclosing medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan without first obtaining an authorization, except as specified in law. (Civil Code 56.10)

3) Provides any physician or surgeon, hospital, pharmacist, nurse, or dentist immunity from liability for any injury sustained by any person by reason of services rendered during any state of war emergency, state of emergency, or a local emergency at the express or implied request of any responsible state or local official or agency. (Gov't Code 8659)

This Bill:

Enacts the Local Pandemic and Emergency Health Preparedness Act of 2006, making various amendments to strengthen and clarify the authority of the health officers in the cases of pandemic and other health emergencies. Among other things the bill would:

1) Authorize a health care, health care service plan, or contractor to disclosing medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan when the information is disclosed to a local health department for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions. (Civil Code 56.10 Amended)

2) Adds podiatrists, psychologists, chiropractors, physical therapists, optometrists, clinical therapists, and marriage and family therapists to the list of healthcare providers that may immunity from liability for any injury sustained by any person by reason of services rendered during any state of war emergency, state of emergency, or a local emergency at the express or implied request of any responsible state or local official or agency; deletes pharmacist and hospitals from the list of healthcare providers. (Gov't Code 8659 Amended)

3) Requires that during an outbreak of communicable disease, or upon the imminent threat of communicable disease outbreak or epidemic that threatens the public's health, all health care providers, clinics, health care service plans, pharmacies, their suppliers, distributors, and other for-profit and nonprofit entities shall disclose inventories of critical medical supplies, equipment, pharmaceuticals, vaccines, or other products requested by a local health officer that may be used for the prevention of or may be implicated in the transmission of communicable disease to the local health officer. The local health officer shall keep this proprietary information confidential. (H&S 120176 Added)

Comment:

1) Author's Intent. The author's intent is to expand the authority of local health officers to act rapidly in the event of an emergency such as, pandemic influenza outbreak or a bioterrorism attack.

2) Suggested Amendment: Correct a drafting error in Gov't Code 8659 to add pharmacists and hospitals back to the list of heath care providers that are immune from liability by any person by reason of services rendered during any state of war emergency.

3) History.

2006

Apr. 6	From committee: Do pass as amended, but first amend, and re-refer to Com. on RLS. (Ayes 8. Noes 0. Page 3481.)
Mar. 28	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 24	Hearing postponed by committee. Set for hearing April 5.
Mar. 10	Set for hearing March 29.
Mar. 2	To Com. on HEALTH.
Feb. 23	From print. May be acted upon on or after March 25.
Feb. 22	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE MARCH 28, 2006

SENATE BILL No. 1430

Introduced by Senator Alquist

February 22, 2006

An act to amend Section ~~100106 of~~ *56.10 of the Civil Code, to amend Section 8659 of the Government Code, and to amend Section 100106 of, and to add Sections 101080.1, 101080.2, and 120176 to,* the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1430, as amended, Alquist. ~~Public health.~~ *The Local Pandemic and Emergency Health Preparedness Act of 2006.*

~~Existing~~

(1) Existing law prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, as specified, or as otherwise required or authorized by law. Violations of these provisions are subject to a civil action for compensatory and punitive damages, and if a violation results in economic loss or personal injury to a patient, it is punishable as a misdemeanor.

This bill would authorize a provider of health care or a health care service plan to disclose the medical information to a local health department for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events, and the conduct of public health

surveillance, public health investigations, and public health interventions.

(2) Existing law provides any physician or surgeon, hospital, pharmacist, nurse, or dentist immunity from liability for any injury sustained by any person by reason of services rendered during any state of war emergency, state of emergency, or a local emergency at the express or implied request of any responsible state or local official or agency.

This bill would include within this immunity any health care provider, as defined to include, among others, podiatrists, psychologists, chiropractors, and marriage and family therapists.

(3) Existing law authorizes the Director of Health Services and local health officers to issue orders to enforce various health and safety requirements. Existing law also authorizes local peace officers to enforce the orders of the State Department of Health Services and of local health officers issued for the purpose of preventing the spread of any contagious, infectious, or communicable disease and authorizes the state director and the local health officer to consider whether a request for enforcement assistance would necessitate advising regarding measures to be taken to prevent infection of enforcement officers when requesting assistance in enforcement of their orders.

This bill would require the State Department of Health Services to annually report to the Legislature on the number of instances when the department requests enforcement assistance from local peace officers under these provisions.

This bill would also authorize a local health officer, in the event of potential human exposures to biological, chemical, toxic, or radiological agents that may spread to others and require immediate action, to issue an order, which shall be in effect for a period not longer than 2 hours, to first responders for the purposes of immediately isolating exposed individuals. The bill would authorize the local health officer, if he or she determines within the 2-hour period, that decontamination or continued isolation of an exposed individual is necessary to protect the public health, to require that the exposed individual remain isolated for a reasonable period of time necessary to protect the public health, or to undergo decontamination, or both. The bill would make a violation of an order issued pursuant to those provisions a misdemeanor, punishable by a fine of up to $1,000, or imprisonment in the county jail for a period of up to 90 days, or both.

(4) Existing law authorizes, in the event of a release, spill, escape, or entry of hazardous waste or medical waste that meets certain requirements, the Director of Health Services to declare a health emergency and the local health officer to declare a county health emergency in the county or any area thereof affected by the threat to the public health. Whenever a local health emergency is declared by a local health officer pursuant to these provisions, the local health emergency is prohibited from remaining in effect for a period in excess of 7 days unless it has been ratified by the board of supervisors, as specified.

This bill would also authorize the director to declare a health emergency and the local health officer to declare a county health emergency in the county or any affected area whenever there is a presence or threat of the introduction of any contagious, infectious, or communicable disease, chemical agent, noncommunicable biologic agent, toxin, or radioactive agent.

(5) Existing law requires each health officer knowing or having reason to believe that any case of the diseases made reportable by regulation of the State Department of Health Services, or any other contagious, infectious, or communicable disease exists, or has recently existed, within the territory under his or her jurisdiction, to take measures as may be necessary to prevent the spread of the disease or occurrence of additional cases. Violation of this provision is a misdemeanor.

This bill would require each health officer to take reasonable measures as may be necessary to prevent the occurrence and spread of human disease or adverse health conditions caused by any serious or life threatening contagious, infectious, or communicable disease, chemical agent, noncommunicable biologic agent, toxin, or radioactive agent.

This bill would also require, during an outbreak of a communicable disease, or upon the imminent threat of a communicable disease outbreak, or epidemic that threatens the public's health, all health care providers, health clinics, health care service plans, pharmacies, and their suppliers, distributors, and other for-profit and nonprofit entities to disclose inventories of critical medical supplies, equipment, pharmaceuticals, vaccines, or other products requested by a local health official for use in the prevention of, or may be implicated in the transmission of, communicable disease to the local health officer.

By changing the definition of a crime and by increasing the duties of local officers, this bill would impose a state-mandated local program.

(6) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that with regard to certain mandates no reimbursement is required by this act for a specified reason.

With regard to any other mandates, this bill would provide that, if the Commission on State Mandates determines that the bill contains costs so mandated by the state, reimbursement for those costs shall be made pursuant to the statutory provisions noted above.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: ~~no~~ *yes*.

The people of the State of California do enact as follows:

SECTION 1. This act shall be known, and may be cited as The Local Pandemic and Emergency Health Preparedness Act of 2006.

SEC. 2. Section 56.10 of the Civil Code is amended to read:

56.10. (a) No provider of health care, health care service plan, or contractor shall disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan without first obtaining an authorization, except as provided in subdivision (b) or (c).

(b) A provider of health care, a health care service plan, or a contractor shall disclose medical information if the disclosure is compelled by any of the following:

(1) By a court pursuant to an order of that court.

(2) By a board, commission, or administrative agency for purposes of adjudication pursuant to its lawful authority.

(3) By a party to a proceeding before a court or administrative agency pursuant to a subpoena, subpoena duces tecum, notice to appear served pursuant to Section 1987 of the Code of Civil Procedure, or any provision authorizing discovery in a proceeding before a court or administrative agency.

(4) By a board, commission, or administrative agency pursuant to an investigative subpoena issued under Article 2 (commencing

with Section 11180) of Chapter 2 of Part 1 of Division 3 of Title 2 of the Government Code.

(5) By an arbitrator or arbitration panel, when arbitration is lawfully requested by either party, pursuant to a subpoena duces tecum issued under Section 1282.6 of the Code of Civil Procedure, or any other provision authorizing discovery in a proceeding before an arbitrator or arbitration panel.

(6) By a search warrant lawfully issued to a governmental law enforcement agency.

(7) By the patient or the patient's representative pursuant to Chapter 1 (commencing with Section 123100) of Part 1 of Division 106 of the Health and Safety Code.

(8) By a coroner, when requested in the course of an investigation by the coroner's office for the purpose of identifying the decedent or locating next of kin, or when investigating deaths that may involve public health concerns, organ or tissue donation, child abuse, elder abuse, suicides, poisonings, accidents, sudden infant death, suspicious deaths, unknown deaths, or criminal deaths, or when otherwise authorized by the decedent's representative. Medical information requested by the coroner under this paragraph shall be limited to information regarding the patient who is the decedent and who is the subject of the investigation and shall be disclosed to the coroner without delay upon request.

(9) When otherwise specifically required by law.

(c) A provider of health care or a health care service plan may disclose medical information as follows:

(1) The information may be disclosed to providers of health care, health care service plans, contractors, or other health care professionals or facilities for purposes of diagnosis or treatment of the patient. This includes, in an emergency situation, the communication of patient information by radio transmission or other means between emergency medical personnel at the scene of an emergency, or in an emergency medical transport vehicle, and emergency medical personnel at a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

(2) The information may be disclosed to an insurer, employer, health care service plan, hospital service plan, employee benefit plan, governmental authority, contractor, or any other person or

entity responsible for paying for health care services rendered to the patient, to the extent necessary to allow responsibility for payment to be determined and payment to be made. If (A) the patient is, by reason of a comatose or other disabling medical condition, unable to consent to the disclosure of medical information and (B) no other arrangements have been made to pay for the health care services being rendered to the patient, the information may be disclosed to a governmental authority to the extent necessary to determine the patient's eligibility for, and to obtain, payment under a governmental program for health care services provided to the patient. The information may also be disclosed to another provider of health care or health care service plan as necessary to assist the other provider or health care service plan in obtaining payment for health care services rendered by that provider of health care or health care service plan to the patient.

(3) The information may be disclosed to any person or entity that provides billing, claims management, medical data processing, or other administrative services for providers of health care or health care service plans or for any of the persons or entities specified in paragraph (2). However, no information so disclosed shall be further disclosed by the recipient in any way that would be violative of this part.

(4) The information may be disclosed to organized committees and agents of professional societies or of medical staffs of licensed hospitals, licensed health care service plans, professional standards review organizations, independent medical review organizations and their selected reviewers, utilization and quality control peer review organizations as established by Congress in Public Law 97-248 in 1982, contractors, or persons or organizations insuring, responsible for, or defending professional liability that a provider may incur, if the committees, agents, health care service plans, organizations, reviewers, contractors, or persons are engaged in reviewing the competence or qualifications of health care professionals or in reviewing health care services with respect to medical necessity, level of care, quality of care, or justification of charges.

(5) The information in the possession of any provider of health care or health care service plan may be reviewed by any private or public body responsible for licensing or accrediting the

provider of health care or health care service plan. However, no patient-identifying medical information may be removed from the premises except as expressly permitted or required elsewhere by law, nor shall that information be further disclosed by the recipient in any way that would violate this part.

(6) The information may be disclosed to the county coroner in the course of an investigation by the coroner's office when requested for all purposes not included in paragraph (8) of subdivision (b).

(7) The information may be disclosed to public agencies, clinical investigators, including investigators conducting epidemiologic studies, health care research organizations, and accredited public or private nonprofit educational or health care institutions for bona fide research purposes. However, no information so disclosed shall be further disclosed by the recipient in any way that would disclose the identity of any patient or be violative of this part.

(8) A provider of health care or health care service plan that has created medical information as a result of employment-related health care services to an employee conducted at the specific prior written request and expense of the employer may disclose to the employee's employer that part of the information that:

(A) Is relevant in a lawsuit, arbitration, grievance, or other claim or challenge to which the employer and the employee are parties and in which the patient has placed in issue his or her medical history, mental or physical condition, or treatment, provided that information may only be used or disclosed in connection with that proceeding.

(B) Describes functional limitations of the patient that may entitle the patient to leave from work for medical reasons or limit the patient's fitness to perform his or her present employment, provided that no statement of medical cause is included in the information disclosed.

(9) Unless the provider of health care or health care service plan is notified in writing of an agreement by the sponsor, insurer, or administrator to the contrary, the information may be disclosed to a sponsor, insurer, or administrator of a group or individual insured or uninsured plan or policy that the patient seeks coverage by or benefits from, if the information was

created by the provider of health care or health care service plan as the result of services conducted at the specific prior written request and expense of the sponsor, insurer, or administrator for the purpose of evaluating the application for coverage or benefits.

(10) The information may be disclosed to a health care service plan by providers of health care that contract with the health care service plan and may be transferred among providers of health care that contract with the health care service plan, for the purpose of administering the health care service plan. Medical information may not otherwise be disclosed by a health care service plan except in accordance with the provisions of this part.

(11) Nothing in this part shall prevent the disclosure by a provider of health care or a health care service plan to an insurance institution, agent, or support organization, subject to Article 6.6 (commencing with Section 791) of Part 2 of Division 1 of the Insurance Code, of medical information if the insurance institution, agent, or support organization has complied with all requirements for obtaining the information pursuant to Article 6.6 (commencing with Section 791) of Part 2 of Division 1 of the Insurance Code.

(12) The information relevant to the patient's condition and care and treatment provided may be disclosed to a probate court investigator engaged in determining the need for an initial conservatorship or continuation of an existent conservatorship, if the patient is unable to give informed consent, or to a probate court investigator, probation officer, or domestic relations investigator engaged in determining the need for an initial guardianship or continuation of an existent guardianship.

(13) The information may be disclosed to an organ procurement organization or a tissue bank processing the tissue of a decedent for transplantation into the body of another person, but only with respect to the donating decedent, for the purpose of aiding the transplant. For the purpose of this paragraph, the terms "tissue bank" and "tissue" have the same meaning as defined in Section 1635 of the Health and Safety Code.

(14) The information may be disclosed when the disclosure is otherwise specifically authorized by law, such as the voluntary reporting, either directly or indirectly, to the federal Food and

Drug Administration of adverse events related to drug products or medical device problems.

(15) Basic information, including the patient's name, city of residence, age, sex, and general condition, may be disclosed to a state or federally recognized disaster relief organization for the purpose of responding to disaster welfare inquiries.

(16) The information may be disclosed to a third party for purposes of encoding, encrypting, or otherwise anonymizing data. However, no information so disclosed shall be further disclosed by the recipient in any way that would be violative of this part, including the unauthorized manipulation of coded or encrypted medical information that reveals individually identifiable medical information.

(17) For purposes of disease management programs and services as defined in Section 1399.901 of the Health and Safety Code, information may be disclosed as follows: (A) to any entity contracting with a health care service plan or the health care service plan's contractors to monitor or administer care of enrollees for a covered benefit, provided that the disease management services and care are authorized by a treating physician, or (B) to any disease management organization, as defined in Section 1399.900 of the Health and Safety Code, that complies fully with the physician authorization requirements of Section 1399.902 of the Health and Safety Code, provided that the health care service plan or its contractor provides or has provided a description of the disease management services to a treating physician or to the health care service plan's or contractor's network of physicians. Nothing in this paragraph shall be construed to require physician authorization for the care or treatment of the adherents of any well-recognized church or religious denomination who depend solely upon prayer or spiritual means for healing in the practice of the religion of that church or denomination.

(18) The information may be disclosed to a local health department for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions.

(d) Except to the extent expressly authorized by the patient or enrollee or subscriber or as provided by subdivisions (b) and (c), no provider of health care, health care service plan, contractor, or corporation and its subsidiaries and affiliates shall intentionally share, sell, use for marketing, or otherwise use any medical information for any purpose not necessary to provide health care services to the patient.

(e) Except to the extent expressly authorized by the patient or enrollee or subscriber or as provided by subdivisions (b) and (c), no contractor or corporation and its subsidiaries and affiliates shall further disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan or insurer or self-insured employer received under this section to any person or entity that is not engaged in providing direct health care services to the patient or his or her provider of health care or health care service plan or insurer or self-insured employer.

SEC. 3. Section 8659 of the Government Code is amended to read:

8659. ~~Any physician or surgeon (whether licensed in this state or any other state), hospital, pharmacist, nurse, or dentist~~ *(a) Any health care provider* who renders services during any state of war emergency, a state of emergency, or a local emergency at the express or implied request of any responsible state or local official or agency shall have no liability for any injury sustained by any person by reason of such services, regardless of how or under what circumstances or by what cause such injuries are sustained; provided, however, that the immunity herein granted shall not apply in the event of a willful act or omission.

(b) "Health care provider" means any of the following:

(1) A health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

(2) A clinic licensed pursuant to Chapter 1 (commencing with Section 1200) of Division 2 of the Health and Safety Code.

(3) A home health agency licensed pursuant to Chapter 8 (commencing with Section 1725) of Division 2 of the Health and Safety Code.

(4) A physician and surgeon licensed pursuant to Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code or pursuant to the Osteopathic Act.

(5) A podiatrist licensed pursuant to Article 22 (commencing with Section 2460) of Chapter 5 of Division 2 of the Business and Professions Code.

(6) A dentist licensed pursuant to Chapter 4 (commencing with Section 1600) of Division 2 of the Business and Professions Code.

(7) A psychologist licensed pursuant to Chapter 6.6 (commencing with Section 2900) of Division 2 of the Business and Professions Code.

(8) An optometrist licensed pursuant to Chapter 7 (commencing with Section 3000) of Division 2 of the Business and Professions Code.

(9) A chiropractor licensed pursuant to the Chiropractic Initiative Act.

(10) A marriage and family therapist licensed pursuant to Chapter 13 (commencing with Section 4980) of Division 2 of the Business and Professions Code.

(11) A clinical social worker licensed pursuant to Chapter 14 (commencing with Section 4900) of Division 2 of the Business and Professions Code.

(12) A physical therapist licensed pursuant to Chapter 5.7 (commencing with Section 2600) of Division 2 of the Business and Professions Code.

~~SECTION 1.~~

SEC. 4. Section 100106 of the Health and Safety Code is amended to read:

100106. (a) Pursuant to Section 11158 of the Government Code, the sheriff of each county, or city and county, may enforce within the county, or the city and county, all orders of the State Department of Health Services issued for the purpose of preventing the spread of any contagious, infectious, or communicable disease. Every peace officer of every political subdivision of the county, or city and county, may enforce within the area subject to his or her jurisdiction all orders of the State Department of Health Services issued for the purpose of preventing the spread of any contagious, infectious, or communicable disease. This section is not a limitation on the

authority of peace officers or public officers to enforce orders of the State Department of Health Services. When deciding whether to request this assistance in enforcement of its orders, the State Department of Health Services may consider whether it would be necessary to advise the enforcement agency of any measures that should be taken to prevent infection of the enforcement officers.

(b) The State Department of Health Services shall report annually to the Legislature on the number of instances when the department requests the enforcement assistance described in this section.

SEC. 5. Section 101080.1 is added to the Health and Safety Code, to read:

101080.1. (a) Whenever there is a presence or threat of the introduction of any contagious, infectious, or communicable disease, chemical agent, noncommunicable biologic agent, toxin, or radioactive agent, the director may declare a health emergency and the local health officer may declare a local emergency in the county or any area thereof affected by the threat to the public health. Whenever a local emergency is declared by a local health officer pursuant to this section, the local emergency shall not remain in effect for a period in excess of seven days unless it has been ratified by the board of supervisors. Thereafter the board of supervisors shall review, at least every 14 days until the local emergency is terminated, the need for continuing the local emergency and shall proclaim the termination of the local health emergency at the earliest possible date that conditions warrant the termination.

(b) After a declaration of a local emergency pursuant to this section, the director or local health officer may do both of the following:

(1) Provide information related to the emergency, or any necessary portions thereof, to the state or local agencies responding to the local emergency or county local emergency or to medical and other professional personnel treating victims of the local emergency.

(2) Sample, analyze, or otherwise determine the identifying and other technical information relating to the local emergency as necessary to respond to or abate the county health emergency and protect the public health.

SEC. 6. Section 101080.2 is added to the Health and Safety Code, to read:

101080.2. (a) In the event of potential human exposures to biological, chemical, toxic, or radiological agents that may spread to others and require immediate action, including, but not limited to, decontamination, the local health officer may issue an order to first responders for the purpose of immediately isolating exposed individuals. An order issued pursuant to this section shall not be in effect for a period longer than two hours. If within the two-hour period the local health officer determines that decontamination or continued isolation of an exposed individual is necessary to protect the public health, the local health officer may require that the exposed individuals remain isolated for a reasonable period of time necessary to protect the public health, or undergo decontamination, or both.

(b) A violation of an order issued pursuant to subdivision (a) is a misdemeanor, punishable by a fine of up to one thousand dollars ($1000), or by imprisonment in the county jail for a period of up to 90 days, or by both.

SEC. 7. Section 120176 is added to the Health and Safety Code, to read:

120176. (a) In order to prevent human disease or adverse health conditions in the territory in his or her jurisdiction caused by any serious or life threatening contagious, infectious, or communicable disease, chemical agent, noncommunicable biologic agent, toxin, or radioactive agent, each health officer shall take reasonable measures as may be necessary to prevent the occurrence and spread of the disease or adverse health conditions.

(b) During an outbreak of communicable disease, or upon the imminent threat of communicable disease outbreak or epidemic that threatens the public's health, all health care providers, clinics, health care service plans, pharmacies, their suppliers, distributors, and other for-profit and nonprofit entities shall disclose inventories of critical medical supplies, equipment, pharmaceuticals, vaccines, or other products requested by a local health officer that may be used for the prevention of or may be implicated in the transmission of communicable disease to the local health officer. The local health officer shall keep this proprietary information confidential.

SEC. 8. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution for certain costs that may be incurred by a local agency or school district because, in that regard, this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

However, if the Commission on State Mandates determines that this act contains other costs mandated by the state, reimbursement to local agencies and school districts for those costs shall be made pursuant to Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1683 **VERSION: INTRODUCED**

AUTHOR: SCOTT **SPONSOR: CALPRIG**

RECOMMENDED POSITION:

SUBJECT: PHARMACEUTICAL INFORMATION: CLINICAL TRIAL DATA

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establish the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufacturers about adverse drug reactions.

This Bill:

1) Establishes the Pharmaceutical Drug Right-to-Know Act. (B&P 30650 Added)

2) Defines the following terms: adverse events, clinical trial, comparator drug, completion date, Initiation date, pharmaceutical company, pharmaceutical drug, principal sponsors, purposes of the trial, outcomes of the trial, outcomes to be tested, and trial funding sources. (B&P 130651 Added)

3) Requires any pharmaceutical company that sells, delivers, offers for sale, or gives away any pharmaceutical drug within this state to make publicly available every new and ongoing clinical trial and every completed clinical trial, that the company conducts or sponsors for every pharmaceutical drug that the company sells, delivers, offers for sale, or gives away in this state.

Requires clinical trial information includes, but not limited to, all of the following:

- The name of the trial.
- Commercial and chemical name of all pharmaceutical drugs to be tested, including comparator drugs.
- Dosages to be tested for each drug, including dosages of comparator drugs.
- Initiation date and expected completion date of the trial.
- Purposes of the trial, including the medical condition or conditions to be studied.
- Outcomes to be tested, including all time points at which outcome data will be measured.
- Trial funding sources.
- Number of participants to be enrolled.
- A list of all specific characteristics used to include and exclude people as trial participants, such as gender, race, age, preexisting health conditions, and an explanation of why each characteristic was used to include or exclude patients.

- Names and contact information for principal sponsors of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.
- Names and contact information for principal researchers of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.
- Any other information required for clinical trial registration by section 113 of the federal Food and Drug Administration Modernization Act of 1997.

(B&P 130652 & 130653 Added)

4) Requires any pharmaceutical company that sells, delivers, offers for sale, or gives away any pharmaceutical drug within this state shall make publicly available an explanation of noncompletion for any clinical trial that the manufacturer initiates but does not complete for every pharmaceutical drug that the company sells, delivers, offers for sale, or gives away in this state.

Required noncompletion informaiton includes, but not limited to, all of the following:

- The list of information required in B&P 130652.
- Reasons for termination of the trial.
- Number of patients enrolled in the trial on the termination date.
- Frequency, severity, and nature of all adverse events experienced by trial participants.
- If the study involved a comparison of two or more pharmaceutical drugs, all information regarding the relative efficacy of each drug and the relative frequency, severity and nature of all adverse events experienced by trial participants, including participants that did not complete the trial, for each drug.
- How the information regarding adverse events to the study drug is reflected in the package insert for the drug, including direct quotations from the package insert.

(B&P 130654 Added)

5) Requires that pharmaceutical companies post the information required in sections 130652, 130653 & 130654, on www.clinicaltrials.gov a Web Site administered by the National Institutes of Health. The measure also establishes dates by which pharmaceutical companies would be required to post clinical trial information. (B&P 130655 Added)

6) Requires that on or before February 1 of each year beginning February 1, 2008, each company subject to measure submit a report to the Attorney General certifying that it is in compliance with this measure and that the information submitted is accurate and complete.

(B&P 130655 Added)

7) Specifies that pharmaceutical companies that fail to meet all of the requirements of the measure would be deemed a violation of the law and liable for a civil penalty of ____ dollars ($____) per violation. (B&P 130659 Added)

Comment:

1) Author's Intent. The author is concerned about drug safety and the perceived inability of the federal government to take action to warn the public about potentially dangerous drugs.

2) ClinicalTrials.gov. The National Institutes of Health (NIH) developed the Web Site ClinicalTrials.gov in collaboration with the Food and Drug Administration (FDA), as a result of the FDA Modernization Act, which was passed into law in November 1997. The Web Site offers up-to-date information for locating federally and privately supported clinical trials for a wide

range of diseases and conditions. ClinicalTrials.gov currently contains approximately 27,200 clinical studies sponsored by NIH, other federal agencies, and private industry. Studies listed in the database are conducted in all 50 States and in over 120 countries. ClinicalTrials.gov receives over 8 million page views per month and hosts approximately 20,000 visitors daily.

3) Drugmaker's Clinical Trial Internet Portal. In September 2005, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) launched an Internet search portal to provide patients and doctors information on ongoing and completed clinical trials for medications that have been approved for marketing. The search engine establishes links to information posted on pharmaceutical company-owned Web Sites and other commercial or government sponsored Web Sites containing information provided by pharmaceutical companies. Clinical trail results are published within one year after a medication is approved, or for post-approvals, within one year of trial completion. (IFPMA members include the European Federation of Pharmaceutical Industries and Associations, the Japanese Pharmaceutical Manufacturers Associations, and the Pharmaceutical Research and Manufacturers of America.)

4) Other Legislation. AB 71 (Chan) Office of California Drug Safety Watch, would require DHS to 1) establish a central repository of information about the safety and effectiveness of prescription drugs; and 2) disseminate information to health care professionals and consumers through a Web site that would include links to other relevant web-based information that has been professionally reviewed and approved. This bill has been in the Senate Health Committee since June 2005.

SB 380 (Alquist) Drugs: Adverse Event Reporting, would require licensed health professionals and a health facilities to report serious adverse drug events that they observe to MedWatch, the FDA's drug safety information and adverse event reporting program. (MedWatch is a voluntary reporting program that allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use.) SB 380 died in the Assembly last year.

5) History.

2006

Apr. 6	Set for hearing April 19.
Mar. 9	To Com. on HEALTH.
Feb. 27	Read first time.
Feb. 25	From print. May be acted upon on or after March 27.
Feb. 24	Introduced. To Com. on RLS. for assignment. To print.

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SENATE BILL No. 1683

Introduced by Senator Scott

February 24, 2006

An act to add Division 112.6 (commencing with Section 130650) to the Health and Safety Code, relating to pharmaceutical information.

LEGISLATIVE COUNSEL'S DIGEST

SB 1683, as introduced, Scott. Pharmaceutical information: clinical trial data.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of food, drugs, and cosmetics, under the administration of the State Department of Health Services.

This bill would require a pharmaceutical company that sells, delivers, offers for sale, or gives away pharmaceutical drugs within the state to make publicly available every new and ongoing clinical trial, the results of every completed clinical trial, an explanation of noncompletion for any uncompleted clinical trial that the company conducts or sponsors. The bill would authorize the Director of Health Services to adopt additional reporting requirements and would require each subject company to submit an annual report to the Attorney General that certifies that the company is in compliance with the provisions of the bill. The bill would make violation of its provisions subject to a civil penalty of $_____.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. (a) The Legislature finds and declares all of the following:

(1) Recent scandals involving Vioxx, Celebrex, Paxil, and other medications have demonstrated a need for the state to better protect California consumers taking pharmaceutical products.

(2) In some of these scandals, including Vioxx and Paxil, the manufacturers of the drugs had access to clinical trial data demonstrating serious potential adverse side effects or lack of effectiveness, but the manufacturers did not share the data with the general public.

(3) The absence of this information hurts consumers both financially and physically. Research by the federal Food and Drug Administration estimates that Vioxx alone may have caused up to 140,000 cases of coronary heart disease in the United States.

(4) Articles and editorials in leading medical journals and newspapers have highlighted problems with clinical trial reporting beyond outright data suppression, including: the use of a comparison drug at a dosage that is too low to be effective, making the study drug appear superior; the choice of a comparison drug dosage that is too high, making the study drug appear less toxic; the publication of data only from preferential endpoints; the publication of the same data in multiple articles to increase the data's impact; and the use of ghostwriters paid indirectly or directly by the study sponsor to give the sponsor control over the publication's message.

(5) By making sure that all clinical studies on pharmaceutical drugs see the light of day and that the information necessary to understand and critique the studies is available, doctors and other medical professionals will be better equipped to make sound decisions about medicines and patients will be better informed about potential dangers of certain medicines.

(b) It is the intent of the Legislature in enacting this act to require pharmaceutical drug companies to make public the results of all clinical trials conducted on their drugs if those drugs are made available to California consumers.

SEC. 2. Division 112.6 (commencing with Section 130650) is added to the Health and Safety Code, to read:

DIVISION 112.6. PHARMACEUTICAL DRUG RIGHT-TO-KNOW ACT

130650. This division shall be known, and may be cited as the "Pharmaceutical Drug Right-to-Know Act."

130651. For purposes of this chapter, the following definitions shall apply:

(a) "Adverse events" means any negative health outcome occurring in a clinical trial subject during the course of the clinical trial.

(b) "Clinical trial" means a clinical investigation as defined by the federal Food and Drug Administration that involves any experiment to test the safety or efficacy of a drug or biological product with one or more human subjects.

(c) "Comparator drug" means an investigational or marketed drug or placebo against which a new drug is being tested and compared.

(d) "Completion date" means the date of the last patient visit necessary for completion of the trial or the date of the first publication of any data from the clinical trial, whichever is first.

(e) "Initiation date" means date of enrollment for the first patient in a clinical trial.

(f) "Pharmaceutical company" means any entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of pharmaceutical drugs, either directly or indirectly, by means of chemical synthesis or by a combination of extraction and chemical synthesis. "Pharmaceutical company" also means an entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of pharmaceutical drugs. "Pharmaceutical company" also includes a person who engages in pharmaceutical detailing, promotional activities, or other marketing of a pharmaceutical drug in this state on behalf of a pharmaceutical company.

(g) "Pharmaceutical drug" means any drug which is approved by the federal Food and Drug Administration and commercially available in the state.

(h) "Principal sponsors" means the entity ultimately responsible for funding the trial, the entity ultimately responsible for designing the trial protocol, and the entity who owns the data generated by the trial.

(i) "Purposes of the trial" means the hypotheses that the trial is testing, including, but not limited to, all of the following:

(1) The drug's effectiveness in treating a specific illness or condition. In this case, the illness or condition shall be named, and what type of effect is being sought shall be specified.

(2) The drug's safety when used to treat a specific illness or condition. In this case, the illness or condition shall be named.

(3) The relative effectiveness or relative safety of the drug in treating a specific illness or condition as compared to another drug. In this case, the illness or condition shall be named, and the effect or adverse events to be compared shall be specified.

(j) "Outcomes of the trial" means the specific measurements that were taken to evaluate the effects the drug and any comparator drug had on trial participants.

(k) "Outcomes to be tested" means the specific measurements that will be taken to evaluate the effects the drug and any comparator drug have on trial participants.

(l) "Trial funding sources" means the name of and financial contribution amount for each organization, corporation, individual, or other entity that provides any funding for the clinical trial.

130652. Any pharmaceutical company that sells, delivers, offers for sale, or gives away any pharmaceutical drug within this state shall make publicly available, in accordance with Section 130655, every new and ongoing clinical trial that the company conducts or sponsors for every pharmaceutical drug that the company sells, delivers, offers for sale, or gives away in this state. Information required for registration shall include, but not be limited to, all of the following:

(a) The name of the trial.

(b) Commercial and chemical name of all pharmaceutical drugs to be tested, including comparator drugs, if any.

(c) Dosages to be tested for each drug, including dosages of comparator drugs, if any.

(d) Initiation date and expected completion date of the trial.

(e) Purposes of the trial, including the medical condition or conditions to be studied.

(f) Outcomes to be tested, including all time points at which outcome data will be measured.

(g) Trial funding sources.

(h) Number of participants to be enrolled.

(i) A list of all specific characteristics used to include and exclude people as trial participants, such as gender, race, age, preexisting health conditions, and an explanation of why each characteristic was used to include or exclude patients.

(j) Names and contact information for principal sponsors of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(k) Names and contact information for principal researchers of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(*l*) Any other information required for clinical trial registration by section 113 of the federal Food and Drug Administration Modernization Act of 1997.

130653. Any pharmaceutical company that sells, delivers, offers for sale, or gives away any pharmaceutical drug within this state shall make publicly available, in accordance with Section 130655, the results of every completed clinical trial that the company has conducted or sponsored for every pharmaceutical drug that the company sells, delivers, offers for sale, or gives away in this state. Information necessary to meet this requirement shall include, but not be limited to, all of the following:

(a) The name of the trial.

(b) Commercial and chemical name of all pharmaceutical drugs tested, including comparator drugs, if any.

(c) Dosages tested for each drug, including dosages of comparator drugs, if any.

(d) Initiation and completion dates of the trial.

(e) Purposes of the trial, including the medical condition or conditions studied.

(f) Outcomes of the trial including all time points at which outcome data were measured.

(g) Trial funding sources.

(h) Number of patients initially enrolled in the trial.

(i) Number of patients completing the trial.

(j) A list of all specific characteristics used to include and exclude people as trial participants, such as gender, race, age, preexisting health conditions, and an explanation of why each characteristic was used to include or exclude patients.

(k) Names and contact information for principal sponsors of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(*l*) Names and contact information for principal researchers of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(m) Frequency, severity, and nature of all adverse events experienced by trial participants, including participants that did not complete the trial, for each drug.

(n) If the study involved a comparison of two or more pharmaceutical drugs, all information regarding the relative efficacy of each drug and the relative frequency, severity, and nature of all adverse events experienced by trial participants, including participants that did not complete the trial.

(o) If any of the data from the study were published in any form, for each of these publications.

(p) If any of the data from the study were published, the name and employer of each author of the study, including "ghostwriters."

(q) Any financial interest the principal researchers of the study have in the drugs tested or compared in the trial and in the principal sponsors of the trial.

(r) How the information regarding adverse events to the study drug is reflected in the package insert for the drug, including direct quotations from the package insert.

130654. Any pharmaceutical company that sells, delivers, offers for sale, or gives away any pharmaceutical drug within this state shall make publicly available, in accordance with Section 130655, an explanation of noncompletion for any clinical trial that the manufacturer initiates but does not complete for every pharmaceutical drug that the company sells, delivers, offers for sale, or gives away in this state. Information required for an explanation of noncompletion shall include, but not be limited to, all of the following:

(a) The name of the trial.

(b) Commercial and chemical name of all pharmaceutical drugs tested, including comparator drugs.

(c) Dosages tested for each drug including dosages of comparator drugs, if any.

(d) Initiation and termination dates of the trial.

(e) Purposes of the trial, including the medical condition or conditions studied.

(f) Reasons for termination of the trial.

(g) Trial funding sources.

(h) Number of patients initially enrolled in the trial.

(i) Number of patients enrolled in the trial on the termination date.

(j) A list of all specific characteristics used to include and exclude people as trial participants, such as gender race, age, and preexisting health conditions and an explanation of why each characteristic was used to include or exclude patients.

(k) Names and contact information for principal sponsors of the trial. Contact information shall include at least a telephone number, mailing address, and email address for public inquiry.

(*l*) Names and contact information for principal researchers of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(m) Frequency, severity, and nature of all adverse events experienced by trial participants.

(n) If the study involved a comparison of two or more pharmaceutical drugs, all information regarding the relative efficacy of each drug and the relative frequency, severity and nature of all adverse events experienced by trial participants, including participants that did not complete the trial, for each drug.

(o) How the information regarding adverse events to the study drug is reflected in the package insert for the drug, including direct quotations from the package insert.

130655. The information required pursuant to Sections 130652, 130653, and 130654 shall be submitted for inclusion on www.clinicaltrials.gov, the Web site administered by the National Institutes of Health pursuant to section 113 of the federal Food and Drug Administration Modernization Act of 1997, or its successor Web site subject, to all of the following conditions:

(a) For clinical trials with a trial initiation date on or after January 1, 2007, the sponsor of the trial shall submit the information required pursuant to Section 130652 to www.clinicaltrials.gov no later than 21 days after the trial's initiation. For ongoing clinical trials with a trial initiation date

before January 1, 2007, the sponsor of the trial shall submit the information required pursuant to Section 130652 to www.clinicaltrials.gov on or before January 22, 2007.

(b) For clinical trials with a trial completion date on or after January 1, 2007, the sponsor of the trial shall submit the information required pursuant to Section 130653 to www.clinicaltrials.gov on or before 90 days from when the pharmaceutical drug is first sold, delivered, or offered for sale, or given away in the state. The publication information required in subdivisions (o) and (p) of Section 130653 shall be updated promptly whenever data from the trial have been included in a new publication. If the trial was registered when it was initiated, any differences between the information reported at that time and the information being submitted upon completion shall be highlighted and explained.

(c) For clinical trials with a noncompletion date on or after January 1, 2007, the sponsor of the trial shall submit the information required by Section 130654 to www.clinicaltrials.gov no later than 21 days after the trial's noncompletion. For clinical trials with a trial noncompletion date before January 1, 2007, the sponsor of the trial shall submit the required information to www.clinicaltrials.gov on or before January 22, 2007.

130657. All information submitted pursuant to this division shall be in plain English to the maximum extent possible, with the goal of being readily understandable by a person who is not a medical professional.

130658. The Director of Health Services may adopt additional reporting requirements and rules for the implementation of this division.

130659. On or before February 1 of each year beginning February 1, 2008, each company subject to this division shall submit a report to the Attorney General certifying that it is in compliance with this section and that the information submitted is accurate and complete.

130660. Failure by a pharmaceutical company to meet all of the requirements of this division shall be deemed a violation of the law and the pharmaceutical company shall be liable for a civil penalty of ____ dollars ($____) per violation. Each clinical trial registration required by, and each clinical trial results disclosure

required that does not fully comply with, this division shall be considered a separate violation for which the pharmaceutical company is liable. Additionally, each day of each violation shall be considered a separate violation for which the pharmaceutical company is liable.

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